Attachment 14 to Agreed Statement of Facts

#### Case 1:12-cr-00026-SGW Document 5-16 Filed 05/07/12 Page 1 of 1/17 Page 1 of 1/17 Page 1/17 Page

From: REDA

CTEDake/ppd/abbott;nsfREDACTED@abbott.com;smtp

To: REDACTED /lake/ppd/abbott@abbott

Cc: Bcc: Subject:

Date: Wed Oct 29 2003 17:14:42 EST REDACTED<sub>LTC</sub> 102903.ppt

24-25

#### REDACTED

Abbott Laboratories - Pharmaceutical Products Division
Business Unit Director: Neurology, Long Term Care, & Medical Liaisons
REDACTED



## **Depakote Long Term Care**

# 2004 Strategic Investment Proposal

October 30, 2003

## Depakote LTC Strategic Plan Background

### 2003 Depakote LTC

- Revenue: \$129 MM
- Salesforce Efficiency: \$2.4 MM/FTE
- Focus: Skilled Nursing Facilities messaging on agitation/aggression due to historical indication pursuit

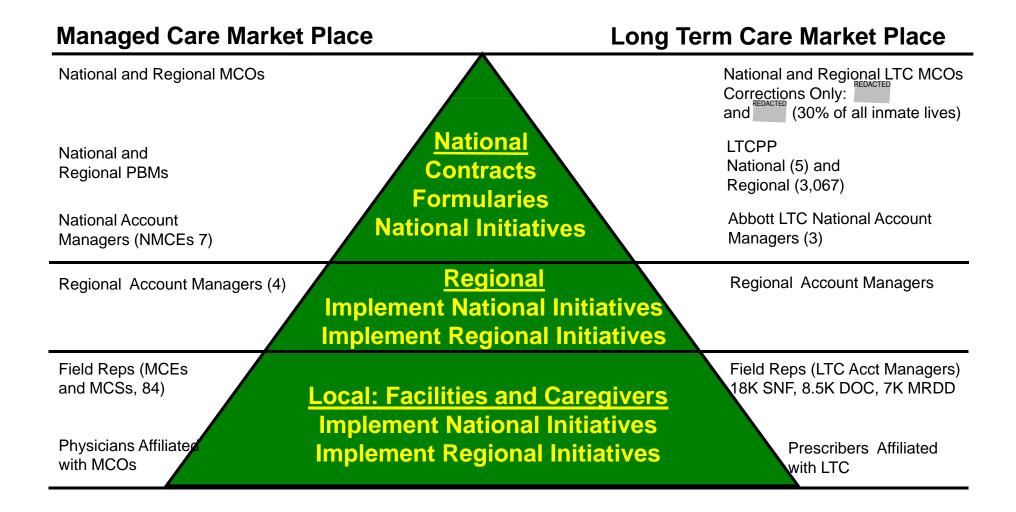
### Q2 2003 Market Research to Explore LTC Growth Opportunities

- MRDD: Mentally Retarded Developmentally Disabled Facilities
  - » Epilepsy and Agitation/Aggression prevalent, 25% and 22% respectively
  - » Once daily Depakote ER advantages: side effects, and med passes.
- DOC: Department of Corrections Facilities
  - » Bipolar and Agitation/Aggression prevalent, 21% and 31% respectively
  - » Once daily Depakote ER advantages: tolerability and med passes.
- SNF: Skilled Nursing Facilities
  - » Bipolar and Epilepsy prevalent, 13% and 10% respectively.

### Q3 2003 HPR Salesforce Analysis

Incremental revenue can be achieved through optimization

## LTC Similarities with Managed Care



Sources:LTC Scenario Data Pull, October 2002; REDACTED

\*The customer universe here was defined by Abbott sales reps (SNAP database) and includes only customers with significant LTC business; thus, for example, the PCP universe here includes only those PCPs that prescribe in SNFs.

## **Depakote LTC Optimization Strategic Objectives**

### Provide incremental revenue and margin

- Incremental revenue of \$120.3 million over LRP
- Incremental margin of \$62.9 million over LRP

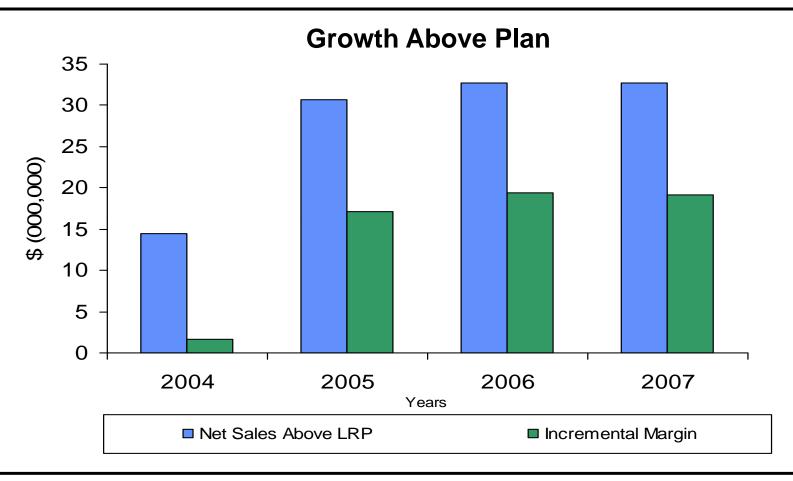
### Reduce promotional risk

- W/O Optimization: Promotion based on agitation/aggression
- With Optimization: Promotion based on epilepsy and bipolar disorder with dissemination of agitation/aggression information.

### Create organization capable of supporting the most profitable segments of LTC

- Marketing and IIS support of SNF, DOC and MRDD
- RAMs to pull through national programs to local level and support regional and independent pharmacy providers
- Sales representatives to cover highest value facilities/caregivers

## Depakote LTC Optimization Can: Provide Incremental Revenue and Margin



Targeted investment in LTC can increase sales by \$120.3 million, with incremental margin of \$62.9 million over the LRP.

Confidential October 27, 2003 Page 4

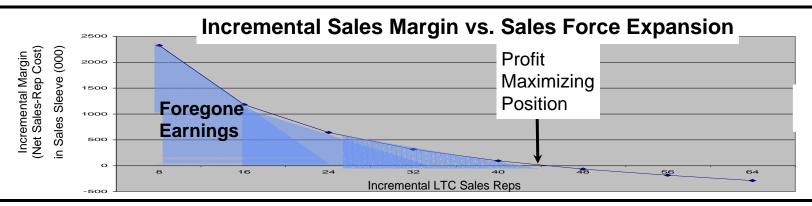
<sup>•</sup> Note: 2004 Reflects the plan numbers. Year 2005-2008 are LRP numbers.

## Three strategic LTC investments are required to deliver incremental revenue of \$120 MM.

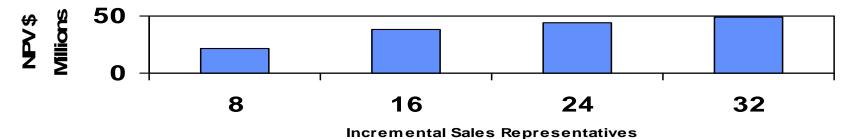
		2004	2005	2006	2007	2008	TOTAL
Sales & Marketing Optimiza	ation						
Sales Force Optimization							
<ul> <li>Increase field based reps from 55 to 79, add 3 DM</li> </ul>							
8 RAMs, 1 RM  Inve	estment	\$7.7MM	\$8.1MM	\$8.2MM	\$8.3MM	\$2.5MM	\$34.8MM
Marketing Expansion							
<ul> <li>Add 2 additional staff and Increase the promotional budget Investory 2.8 MM (Total 38 FTE)</li> </ul>	estment	\$3.2MM	\$3.2MM	\$3.2MM	\$3.2MM	\$1.0MM	\$13.8MM
New Sales		\$14.5	\$29.4	\$29.9	\$31.1	\$8.6	\$112.6
Clinical Data Investment  Fund relevant DOC, MRDD and SNF IIS Inve	estment	\$1.0MM	\$0.5MM	\$0	\$0	\$0	\$1.5MM
New Sa	les	<b>\$0</b>	\$1.3	\$2.8	\$2.5	\$1.1	\$7.7
Total Incremental Sales	<u> </u>	14.5	\$30.7	\$32.7	\$33.6	\$ 9.7	\$120.3
							I - VIV
Total Incremental Investment	•	\$11.9	\$11.8	\$11.4	\$11.5	\$ 3.5	\$50.1

Case 1:12-cr-00026-SGW Document 5-16 Filed 05/07/12 Page 8 of 117 Pageid# Page

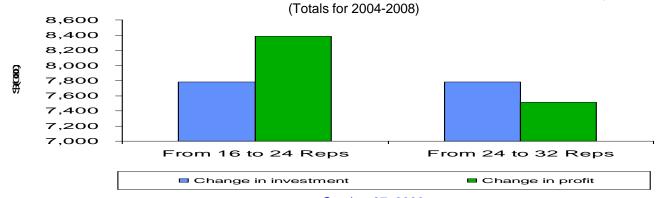
## Sales Force Optimization Analysis: Target Addition of 24 LTC Sales Representatives



#### **NPV** of LTC Optimization



Inflection Point in Investment Decision: Change in Investment vs Change in Profit



### Benchmarking LTC Sales Efficiency: Additional 24 representatives

#### **Local Field Sales Coverage** (FTE Representatives) **Average WAC** \$ Per FTE/ \$ Per FTE/ Per Day of Per Year Per Year **Therapy** (Price Adjusted to WAC) \$2.8 MM \$2.8 MM \$10.69 : 176 FTEs /263 Reps \$9.9 MM \$2.60 Abbott Today: 55 FTES/Reps - \$2.4 MM REDACTED: 80 FTE / 160 Reps \$4.2 MM \$2.0 MM \$5.08 5 NAMs / RAMs unknown **Abbott Proposed Expansion: 79 FTEs/Reps** \$2.60 \$7.8 MM - \$1.9 MM

Sources: REDACTED, Abbott field Interviews, REDACTED primary market research conducted for Abbott in June 2003. FTE counts were achieved by taking 70 % of total rep numbers to account for the primary detail on the atypical antipsychotic.

Confidential October 27, 2003

Page 8

: 188 FTE / 280 Reps

\$2.5 MM

\$1.8 MM

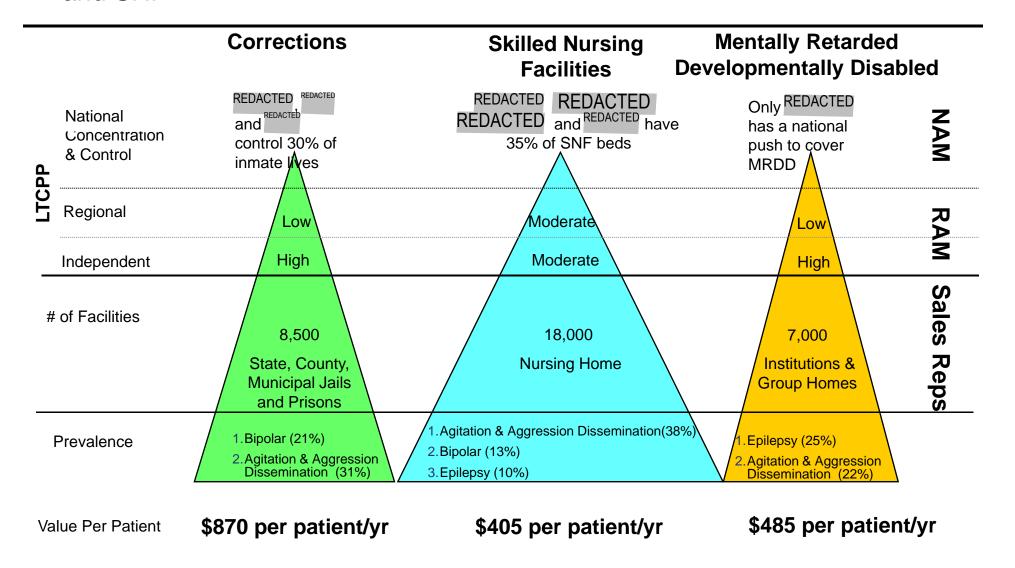
3 NAMs / 8 RAMs

8 NAMs and 10 RAMs for REDACTED alone

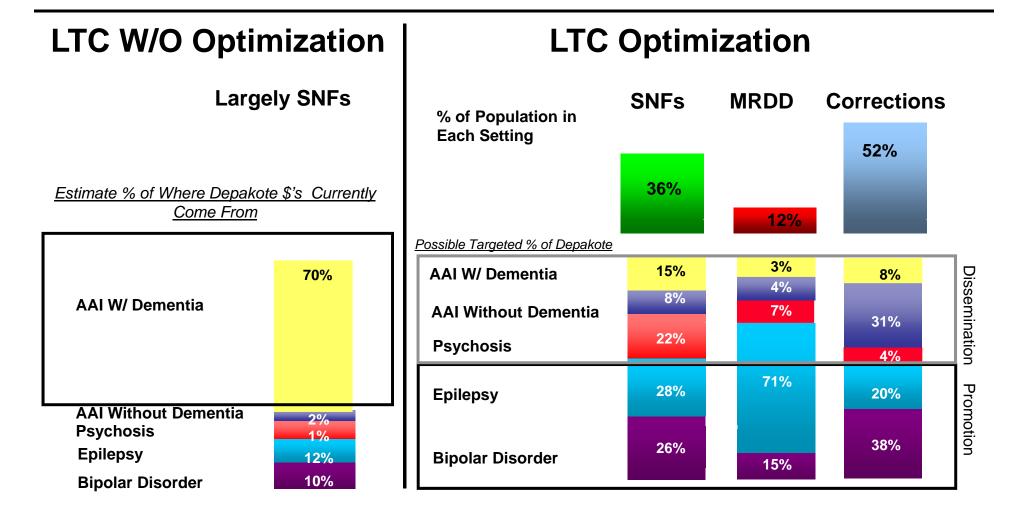
REDACTED

\$7.77

## Depakote LTC Optimization: Expanding focus from SNF to: DOC, MRDD and SNF.



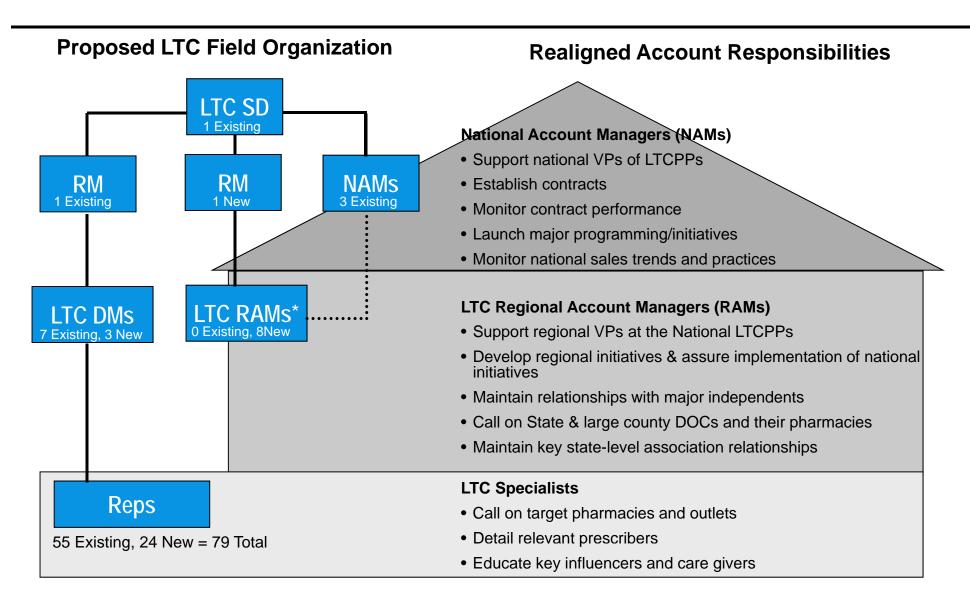
## Depakote LTC Optimization Can: Reduce Promotional Risk



Sources: Current sales by condition from Abbott qualitative analysis. Optimizes sales by condition from REDACTED supplied primary data (QA). Presented results have been rounded from final findings.

Confidential October 27, 2003 Page 10

## New LTC field resources will provide greater coverage within relevant LTC market segments.



## Depakote LTC Optimization Can: Create organization capable of supporting the most profitable segments of LTC

### Summary of Optimization Changes

- Channel align marketing and sales activities to highest opportunity channels within LTC
  - » SNF
  - » MRDD
  - » DOC
- Establish LTC IIS Funding for Channel Specific Studies
  - » 2004
  - » 2005
- Expand pull through organization

» NAM
National Account Management

» RAM
Regional Account Management

» LTC Sales Representative Account based selling

### 2004-2008 P&L Assumptions

#### Sales Force Optimization Includes:

- \$18,000 per rep,\$45,000 per RAM and \$150,000 per NAM war chest allotment
- Voucher allotments per reps can be covered by the current franchise allotment, no samples
- \$168,000 fully loaded costs per year for for reps
- \$259,000 fully loaded costs per year for NAMs, RAMs and DMs
- 40% rep effectiveness in 2004 and 100% effectiveness in remaining years

#### Marketing Expansion Includes:

- A marketeering program budget return of 1.5:1 per Abbott promotional analytical average ROI experience with Abbott marketing programs
- \$207,000 fully loaded costs per year for an SPM
- \$187,000 fully loaded costs per year for PMs

#### Clinical Data Investments Include:

- 75% percent chance of study success
- Similar sales return as produced by the introduction of the two previously incomplete sets of clinical trial data into the SNF market place
- Margin calculations include a 6% reduction for cost of goods sold, freight and other miscellaneous PPD distribution allocations

### **New LTC Clinical Data Will Drive Additional LTC Growth**

## Three substantial investigator initiated studies will drive \$7.7 MM in incremental revenues through 2008, for \$1.5 MM investment.

			2003	2004	2005	2006	2007	2008
Total of three studies Assuming 75% probability of success:		Total Revenue (Current sales force)		\$0.0	\$1.3	\$2.8	\$2.5	\$1.1
		Total Cost		\$1.0	\$0.5			
Detail by strategic componer	nt: Study description:							
As monotherapy, demonstrate efficacy, superior tolerability, and cost-effectiveness vs. atypicals, VPA or other AEDs. As adjunctive therapy, demonstrate efficacy and safety.	IIO Otrada As Daniel ata	Study Revenue (Current sales force)			\$.43	\$.62	\$.56	\$.25
	IIS Study 1: Depakote ER in MRDD	Study Cost		\$0.33	\$0.25			
	IIS Study 2: Depakote ER in DOC	Study Revenue (Current sales force)	••••••••		\$.43	\$1.09	\$.99	\$.44
		Study Cost		\$0.33	\$0.25			
As adjunctive therapy, demonstrate efficacy & safety in patients whose symptoms are inadequately	IIS Study 3: Depakote ER as adjunctive to atypicals in elderly	Study Revenue (Current sales force)	••••••	•	\$.43	\$1.09	\$.99	\$.44
controlled by atypicals	agitation	Study Cost		\$0.33				

## KOLs advise that clinical data specific to each Sector is needed to best impact Depakote business in the DOC and MRDD Markets.

#### For the DOC Sector :

- The DOC represents a unique group of patients with biological and environmental issues contributing to patient condition
- Pharmacological treatment decisions for DOC patients can be different than for those in the general population:
  - » Severity of condition can be greater in the DOC environment
  - » Patient compliance can be more problematic
  - » Consequences of treatment failures more severe
- Studies in the DOC patient population most relevant to practitioners

#### For the MRDD Sector:

- The MRDD patient population is unique and represents a group that can have severe handicaps
- Identification and appropriate classification of patient conditions is problematic due to the patient's inability to articulate symptoms
- Pharmacologic treatment decisions for MRDD patients can be different due to the nature of the patient's condition

### **Proposed IIS LTC Study Descriptions in Correctional Facilities**

#### Conditions Assessed:

- Agitated/Aggressive/Impulsive behaviors with or without head injuries
- (per REDACTED) Bipolar Disorder with at least one comorbidity (have a laundry list that could include:
  - » Agitated/Aggressive/Impulsive behaviors
  - » MRDD
  - » head injury
  - » substance abuse
  - » ADHD
  - Others (DR. REDACTED noted that the design could resemble the abulatory study she is currently doing for Psychiatry Team)

#### Type of Study:

 Prospective (Note: Informed consent requirements and advocacy oversight may require that any prospective study use two active agents.)

#### Study Setting:

- Jails
- Prisons
- Probation catchment (DR REDACTED suggested that if getting IRB approved for prison population is a problem, it
  would be possible to screen probation patients or patients with a prison/jail record)

#### Primary Assessment:

- Efficacy
  - » Improvement in Bipolar
  - » Decreased frequency and severity of behaviors; patients "less triggered" by stressors
  - » Decreased frequency and severity of comorbid condition
- Also measure side effects, safety, tolerability

## Proposed IIS LTC Study Descriptions in Correctional Facilities (continued)

#### Primary endpoints:

- YMRS
- Overt Aggression Scale and others
- Staff keeps log of frequency of behaviors; measure Vs. staff assessment
  - » Use of restraints
  - » Time in isolation or solitary confinement
  - » Number of medication passes required
- Seizure measurement scales
- Other scales relevant to comorbid conditions
- Cost savings due to better compliance, fewer side effects, fewer relapses etc

#### Time period for study:

- Jails: 4 week study
- Prisons: 4 week study (but could be longer due to inmate length of stay)
- Probation: 8 week study

#### Patient Inclusion Criteria:

See primary assessment

#### Treatment Arms:

- Depakote ER vs placebo or Loading dose Depakote ER vs. Non-Loading Dose DepakoteER (per DR. REDACTED)
- Depakote ER Vs. valproic acid
- Depakote ER Vs. an antipsychotic (Zyprexa: could show results and differences in side effect profiles)

### **Proposed IIS LTC Clinical Study Descriptions in MRDD**

#### Conditions assessed:

Agitated/Aggressive/Impulsive behaviors with or without seizures

#### Type of Study:

- Prospective (per MD respondents)
- Retrospective ok (per REDACTED pharmacist)

#### Primary Assessment:

- Efficacy
  - » decrease frequency and severity of behaviors; patients "less triggered" by stressors
  - » decrease frequency and severity of seizures

#### Primary endpoints:

- Overt Aggression Scale and others
- Staff keeps log of frequency of behaviors; measure Vs. staff assessment
- Seizure measurement scales

#### Time period for study:

 3-6 months (it was noted that there is a seasonal response: patients have more behavioral problems in the Spring/Summer versus Fall/Winter. Therefore a study of 1 yr... or more would eliminate the seasonality)

#### Patient Inclusion Criteria:

- Patients are required to have failed behavioral therapy or behavioral therapy must have been ruled out as an option in order to begin pharmacotherapy.
- It was also suggested that patients could be those who previously failed treatment on a low dose of an antipsychotic

#### Treatment Arms:

- Depakote ER Vs. behavioral therapy (double blind)
- Depakote ER Vs. an antipsychotic (Zyprexa: could show results and differences in side effect profiles)
- AP therapy Vs. AP plus Depakote ER
- Depakote ER Vs. another AED

## KOLs also advise that the best development path for Depakote in elderly agitation would be adjunctive studies with atypicals.

- Two major clinical studies of Depakote monotherapy were discontinued, for reasons unrelated to efficacy:
  - M97-738: Depakote in Elderly Mania Showed efficacy<sup>1</sup>, but discontinued in 1999 because of excessive somnolence
    - » Somnolence was caused by dosing schedule that was too aggressive for an elderly population
  - M99-082: Behavioral Agitation in Elderly patients with Dementia Discontinued in 2001 before any results were available, because recruitment targets could not be met at reasonable cost
    - » Recruitment was very slow because inclusion criteria were too restrictive: in particular, patients on antidepressants were excluded, thus reducing the eligible population by around 50%
- Key opinion leaders therefore advise an adjunctive study as the best development path for Depakote in BDD:
  - Investigators unlikely to be willing to conduct further Depakote monotherapy trials, because of prior experiences
  - The adjunctive market is large: Geriatric psychiatry advisors estimate 50-70% of patients require polypharmacy for management of aggression
  - Adjunctive Depakote works: Existing data<sup>2</sup> shows that Depakote + atypical combination is effective in patients unresponsive to monotherapy or taking multiple atypicals
  - Recruitment will be easier: The majority of BDD patients are already treated with antipsychotics, so the eligible population will be large
  - Drop-outs due to adverse events can be minimized: Availability of ER 250 mg and a better understanding of tolerability issues in the elderly means the side-effects caused M97-738 to be discontinued can be avoided

Sources: (1) Tariot *et al.*, Curr. Therapeutic Res. 2001, 62: 51-67; (2) Narayan & Nelson, J. Clin. Psychiatry, 1997, 58: 351-4; M99-082 Study protocol; Draft FDA submission prepared by Abbott proposing label change to Depakote for indication in elderly agitation; Neuroscience clinical team, strategic review document

### Proposed IIS LTC Clinical Study Descriptions in Elderly Agitation

- Conditions assessed:
  - Agitated/Aggressive/Impulsive behaviors with or without seizures
- Type of Study:
  - Prospective open label
- Primary Assessment:
  - Efficacy as measured by the PANSS Excited Component, which includes measurement of the following:
    - » impulse control
    - » tension
    - » hostility
    - » degree of cooperativeness
    - » excitement
- Primary endpoints:
  - PANSS Excited Component
- Time period for study:
  - 12 months
- Patient Inclusion Criteria:
  - Probable or possible Alzheimer's
  - Probable or possible vascular dementia
- Treatment Arms:
  - Depakote ER and atypical, vs. atypical + atypical , vs. atypical alone; n=30-40 each group

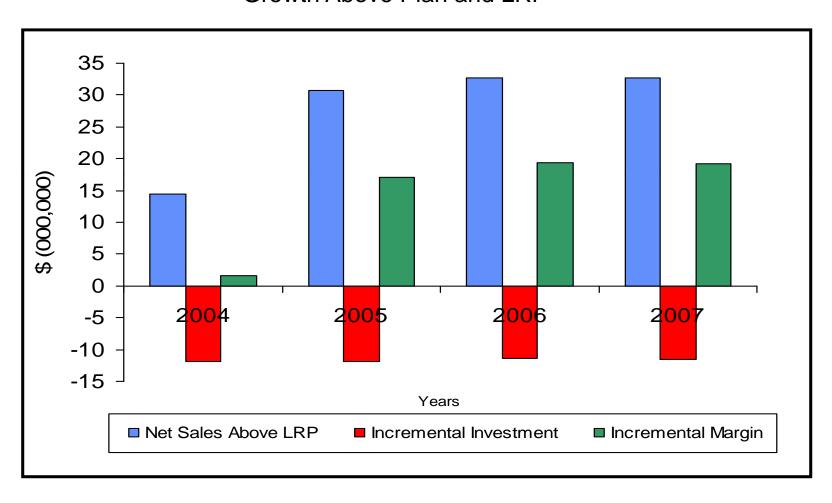
Source: Abbott Conducted Qualitative Research with MLs and Key Opinion Leaders, Fall 2002.

LTC Strategic Investment Summary: Grow sales by focusing on Department of Corrections, Mentally Retarded Developmentally Disabled and Skilled Nursing Facilities.

- Refocus today's largely SNF directed sales and marketing efforts towards a more expansive set of targets: DOC, MRDD and SNF
  - Corrections: deliver core bipolar message
  - Mentally Retarded Developmentally Disabled: deliver core epilepsy message
  - Skilled Nursing Facility: increase bipolar and epilepsy messaging
  - Target all three channels with additional marketing programs
- Generate in 2004: \$14.5 MM in new LTC sales from \$11.9 MM in new investments with a positive margin of \$1.6MM:
  - \$3.2 in additional marketing resources: 2 new FTEs (Channel Aligned to DOC and MRDD) with \$2.8 MM in promotional dollars
  - \$7.7 MM in additional field resources: 24 reps/3 DMs and 8 RAMs/1 RM
  - \$1.0 MM in additional LTC dedicated IIS funding
- Generate \$120 MM in new LTC sales in years 2004-2008 from investment
  - 2005: \$30.7 MM incremental sales: \$17.1 MM incremental margin
  - 2006: \$32.7 MM incremental sales: \$19.4 MM incremental margin
  - 2007: \$32.7 MM incremental sales: \$19.2 MM incremental margin

## Targeted investments in LTC can increase sales over current LRP projections by \$120 in five years.

#### Growth Above Plan and LRP\*



<sup>•</sup> Note: 2004 Reflects the most recent plan numbers. Year 2005-2008 LRP numbers are likely to be updated in December 2003.

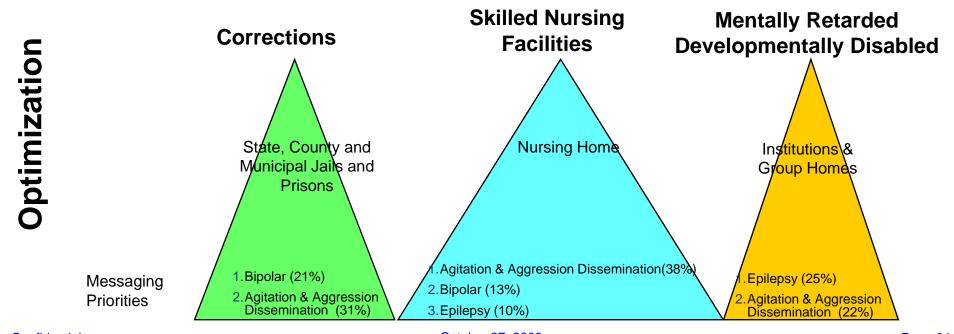
### **Outline**

- Executive Summary of LTC Strategy
- Strategic Investment Proposal Framework
- Targeted LTC Channels
- Sales Force Optimization Summary
- Summary of Financial Analysis

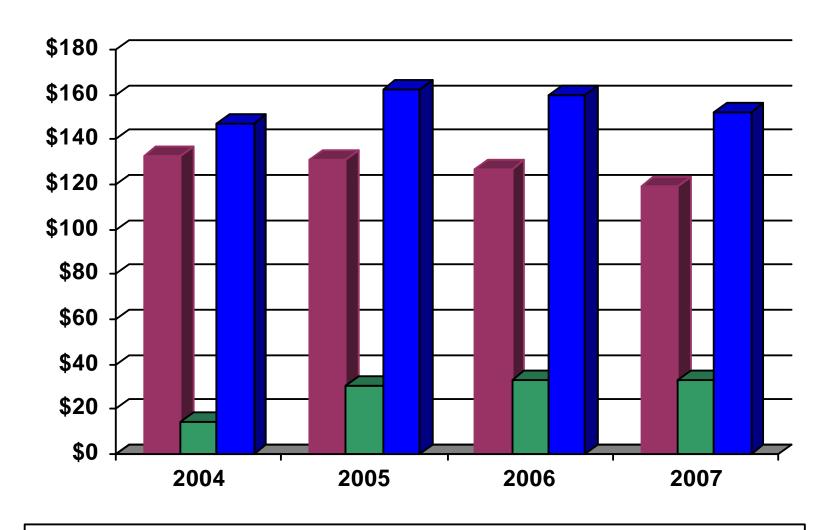
## Depakote LTC Optimization Can: Reduce Promotional Risk







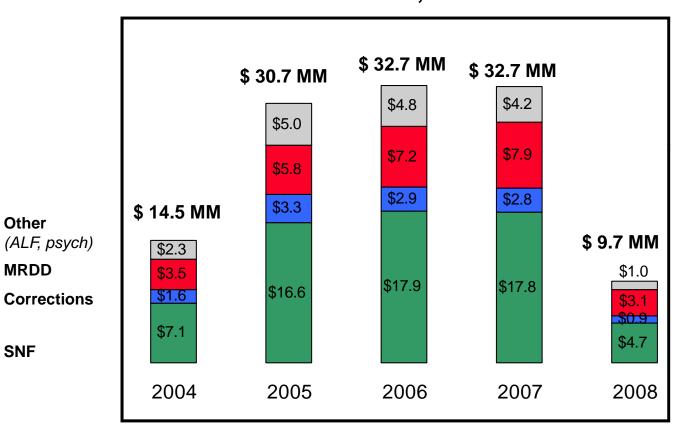
## LTC Optimization Provides Incremental Revenue



■ LRP Sales Forecast ■ Incremental Revenue ■ With LTC Optimization

### Where does the growth come from?

### Change in Revenues Over 2004 Plan, 2005-2008 LRP\*



\*Note: The 2005-2008 LRP will be updated in December 2003.

**SNF** 

#### New LTC Clinical Data Will Drive Additional LTC Growth

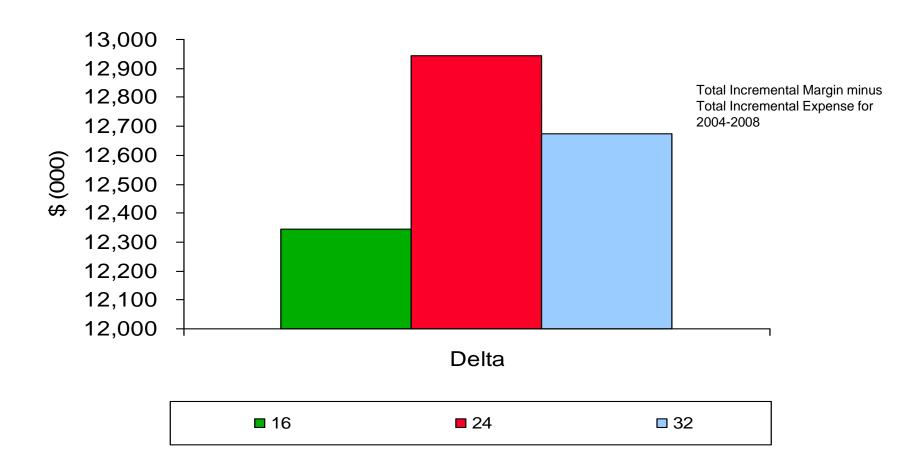
## Three substantial investigator initiated studies will drive \$7.7 MM in incremental revenues through 2008, for \$1.5 MM investment.

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Total of three studies Assuming 75% probability of success:		Total Revenue (Current sales force)		\$0.0	\$1.3	\$2.8	\$2.5	\$1.1
		Total Cost		\$1.0	\$0.5			-
Detail by strategic componer	nt: Study description:							
As monotherapy, demonstrate efficacy, superior tolerability, and cost-effectiveness vs. atypicals, VPA or other AEDs. As adjunctive therapy, demonstrate efficacy and safety.	IIS Study 1: Danakata	Study Revenue (Current sales force)			\$.43	\$.62	\$.56	\$.25
	IIS Study 1: Depakote ER in MRDD	Study Cost		\$0.33	\$0.25			
	IIS Study 2: Depakote ER in DOC	Study Revenue (Current sales force)			\$.43	\$1.09	\$.99	\$.44
		Study Cost		\$0.33	\$0.25			
As adjunctive therapy, demonstrate efficacy & safety in patients whose symptoms are inadequately	IIS Study 3: Depakote ER as adjunctive to atypicals in elderly	Study Revenue (Current sales force)	••••••		\$.43	\$1.09	\$.99	\$.44
controlled by atypicals	agitation	Study Cost		\$0.33				

## Adding 24 additional representatives reaches the inflection point between incremental investment and incremental margin

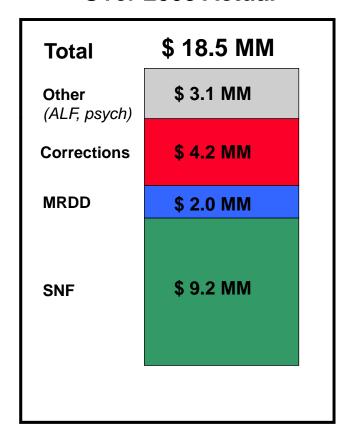
Inflection Point in Investment Decision:

[Total Incremental Contribution Margin-Total Incremental Expense]=Delta



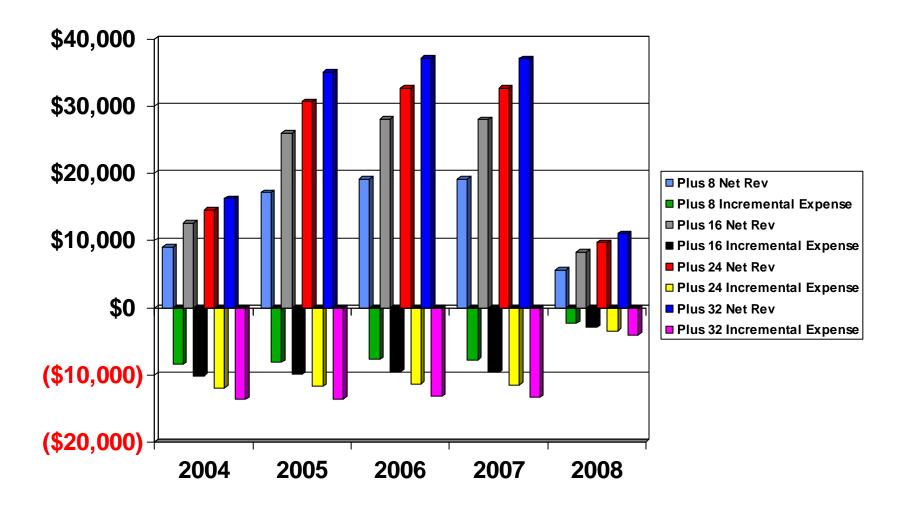
### Where does the LTC growth come from (2003-2004)?

## Change in Revenues Over 2003 Actual



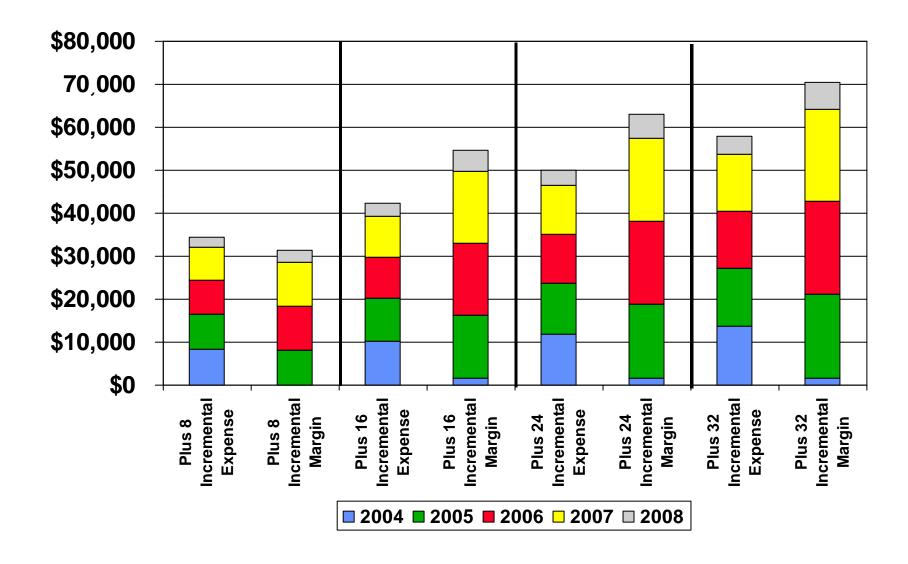
\*Note: The 2005-2008 LRP will be updated in December 2003.

### **Incremental Revenue Compared to Incremental Expenses**

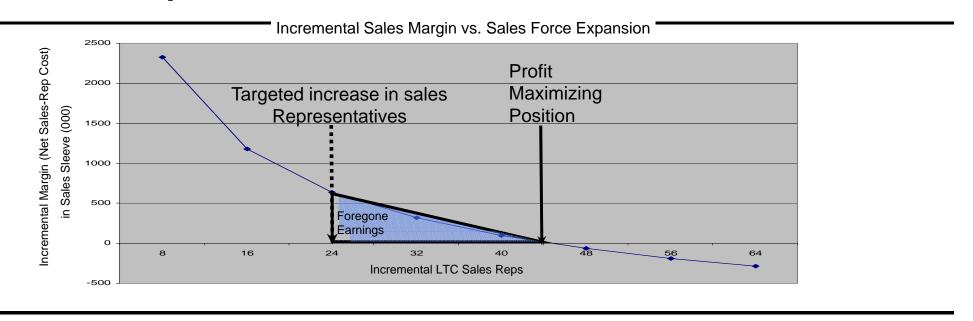


	2004	2005	2000	2007	2000
	2004	2005	2006	2007	2008
Plus 8 Net Rev	\$9,069	\$17,132	\$19,188	\$19,116	\$5,634
Plus 8 Incremental Expense	(\$8,454)	(\$8,151)	(\$7,729)	(\$7,809)	(\$2,367)
Plus 8 Incremental Margin	\$71	\$7,953	\$10,308	\$10,160	\$2,929
Plus 16 Net Rev	\$12,633	\$26,044	\$28,100	\$28,028	\$8,308
Plus 16 Incremental Expense	(\$10,190)	(\$9,951)	(\$9,556)	(\$9,663)	(\$2,931)
Plus 16 Incremental Margin	\$1,685	\$14,530	\$16,858	\$16,683	\$4,878
Plus 24 Net Rev	\$14,493	\$30,692	\$32,748	\$32,676	\$9,702
Plus 24 Incremental Expense	(\$11,927)	(\$11,751)	(\$11,383)	(\$11,517)	(\$3,496)
Plus 24 Incremental Margin	\$1,696	\$17,099	\$19,400	\$19,198	\$5,624
Plus 32 Net Rev	\$16,252	\$35,090	\$37,146	\$37,074	\$11,021
Plus 32 Incremental Expense	(\$13,664)	(\$13,551)	(\$13,210)	(\$13,371)	(\$4,061)
Plus 32 Incremental Margin	\$1,613	\$19,434	\$21,708	\$21,478	\$6,299

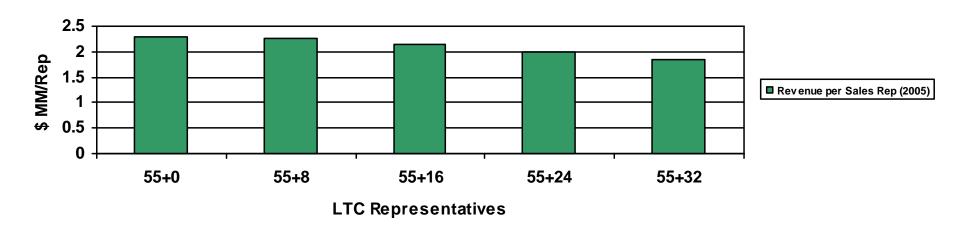
Increasing the size of the salesforce from 16 to 32 representatives never reaches the point of inflection where incremental investment drives equivalent incremental earnings (i.e. the 40+ rep scenario)



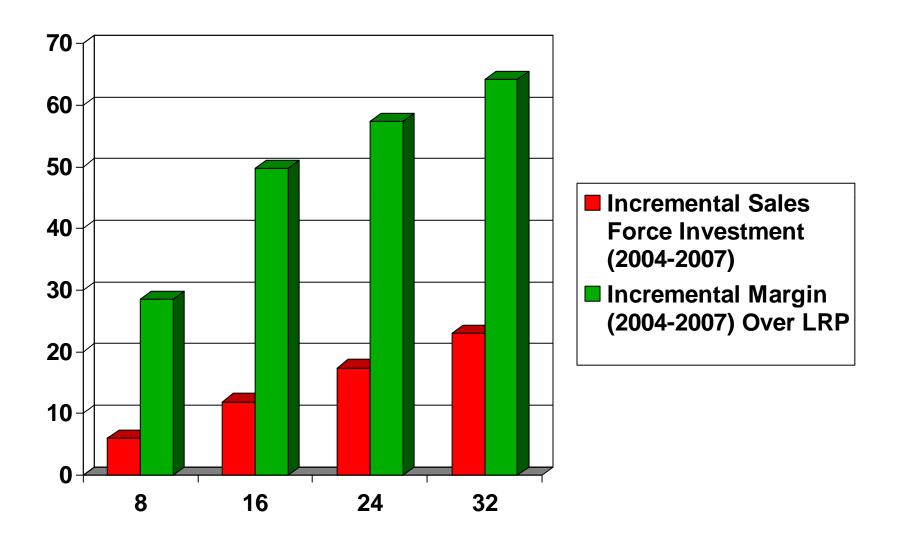
## Sales Force Optimization: Target Addition of 24 LTC Sales Representatives



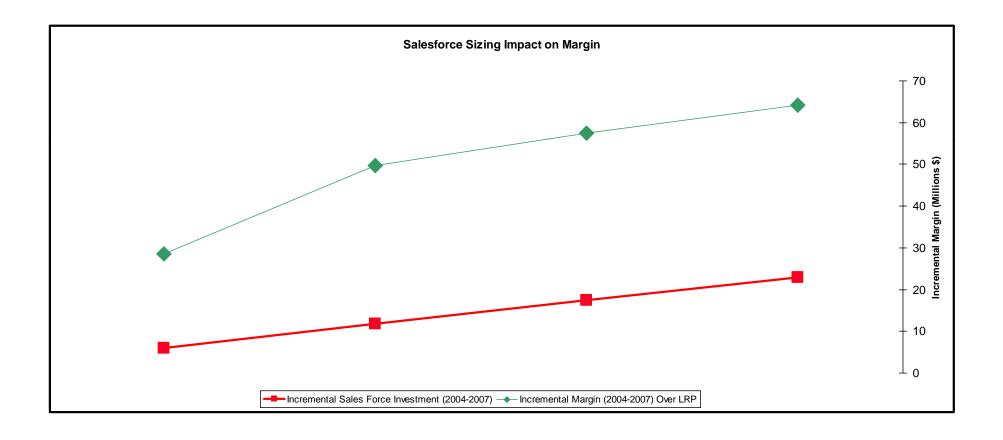
#### 2005 Net Revenue per Sales Rep



## **Incremental Margin Improves Over All Scenarios**



# Sales Force Optimization: Target Addition of 24 LTC Sales Representatives

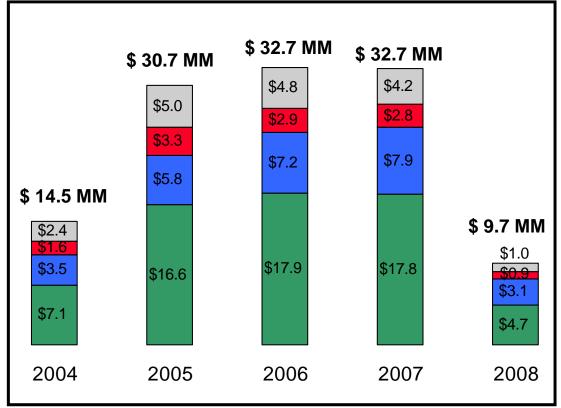


### Where does the growth come from?

## Change in Revenues Over 2003 Actual

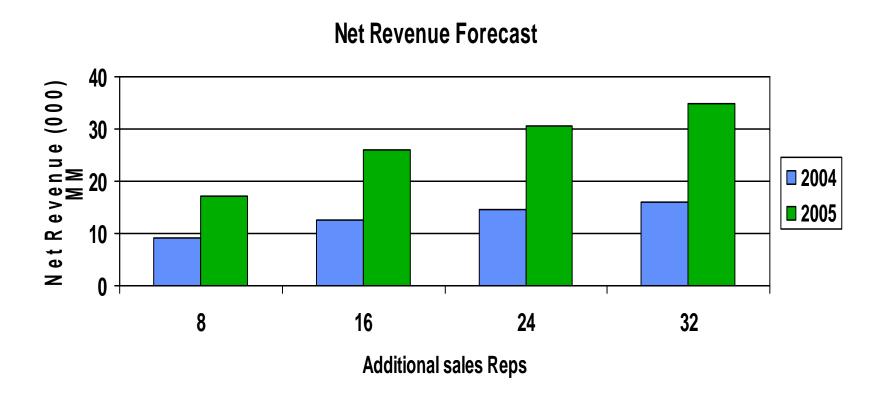
## Change in Revenues Over 2004 Plan, 2005-2008 LRP\*





\*Note: The 2005-2008 LRP will be updated in December 2003.

# Sales Force Optimization: Target Addition of 24 LTC Sales Representatives



# Three strategic LTC investments are need to ensure delivery of \$120 MM in projected new revenues over the next five years.

		2004	2005	2006	2007	2008	TOAL
LTC 2004 Buy-Up Needs	S						
Sales Force Optimization	New Sales	\$9.7MM	\$24.2MM	\$24.2MM	\$24.2MM	\$7.3MM	\$89.6MM
<ul> <li>Increase field based resources from 55 to 77</li> </ul>	Investment	\$7.7MM	\$8.1MM	\$8.2MM	\$8.3MM	\$2.5MM	\$34.8MM
Marketing Expansion							
<ul> <li>Add 2 additional staff and Increase the</li> </ul>	New Sales	\$4.8MM	\$5.2MM	\$5.7MM	\$5.9MM	\$1.3MM	\$23.0MM
promotional budget by 2.8 MM and initiate corrections contracting	Investment	\$3.2MM	\$3.2MM	\$3.2MM	\$3.2MM	\$1.0MM	\$13.8MM
Clinical Data Investment							
<ul> <li>Fund relevant Corrections, MRDD and</li> </ul>	New Sales	\$0	\$1.3MM	\$2.8MM	\$2.5MM	\$1.1MM	\$7.7MM
SNF investigator initiated studies	Investment	\$1.0MM	\$0.5MM	\$0	\$0	\$0	\$1.5MM
	=		<b>^</b>	<b>***</b>	<b></b>	<b>A A B B B B B B B B B B</b>	
TOTAL Sales	<b>\$</b>	14.5 MM	\$30.7 MM	\$32.7 MM	\$32.7 MM	\$ 9.7MM	\$120.3 MM
TOTAL Investment	t \$	11.9 MM	\$11.8 MM	\$11.4 MM	\$11.5 MM	\$ 3.5MM	\$50.1 MM

## **Proposed 2004 LTC Promotional Budget Allocations**

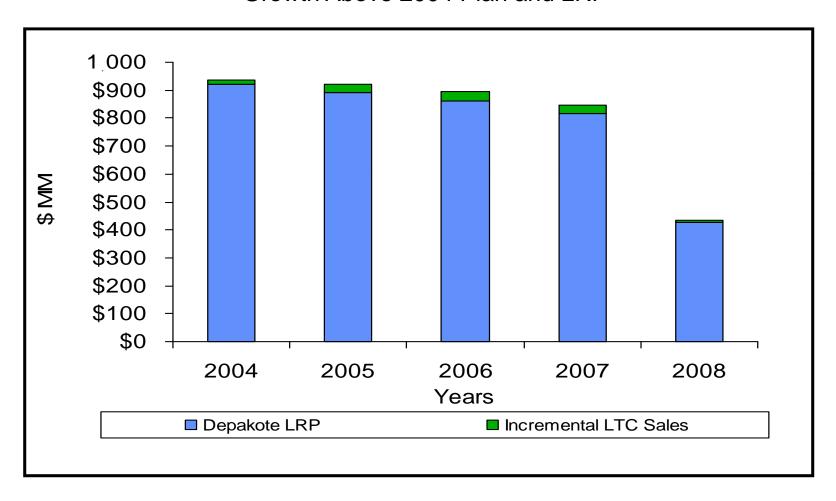
	TOTAL	\$ 2.6	\$ 5.5	
Data Purchases	Syndicated and proprietary data purchases	\$ 0	\$ 300	Annual LTC physician level data, new DNA product and list purchases for Corrections and MRDD
Market Research	Focus Groups, Studies	\$ 225	\$ 400	ATU and positioning research for new strategy
Agency Fees	PR and Advertising Fees	\$ 0	\$ 20	Use external PR support to publicize new findings
Consultant Meetings	One on one meetings with key prescribers/influencers	\$ 0	\$ 675	4 corrections RCMs, 4 MRDD RCMS and SNF DCMs
Grants	Funds for institutes/3rd parties to support product research / foster general company goodwill	\$ 300	\$ 700	Added support to advocacy organizations to produce patient/care giver materials relevanted to Corrections, MRDD and SNF environments.
CME Programs		\$ 400	\$ 1.0	"Key Pharmacoeconomic Concerns in the DOC: Why Branded is Better!", "Differential diagnosis: psychiatric and behavioral disturbances in the mentally retarded and developmentally delayed", "Increased Patient Compliance with QD Dosing."
Meetings and Events	Conventions, Meeting Symposia, Advisory Board	\$ 1.1	\$ 1.7	Reduced SNF meetings, additional Corrections and MRDD Meetings, 2 adviso meetings per market segment
Sales Force Support	Reprints, Sales Aids, and NAM War Chest	\$ 580	\$ 700	2 LTC sales aids, 2-4 slim jim like pieces a increased NAM war chest funds to cover corrections
Major Promotional Categories	Key Category Elements	'03 Actual Spend (000's)	2004 Propos Spend (000's	

 $<sup>^{\</sup>ast}\,$  Full program details by sector are found in the appendix.

Confidential October 27, 2003 Page 39

# Targeted investments in LTC can boost the Depakote molecule LRP \$120 over five years.

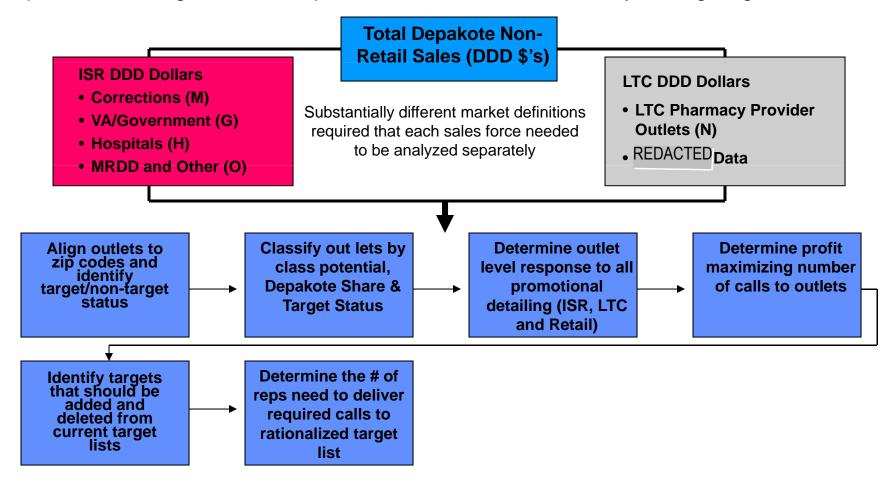
#### Growth Above 2004 Plan and LRP\*



<sup>•</sup> Note: 2004 Reflects the most recent plan numbers. Year 2005-2008 LRP numbers are likely to be updated in December 2003.

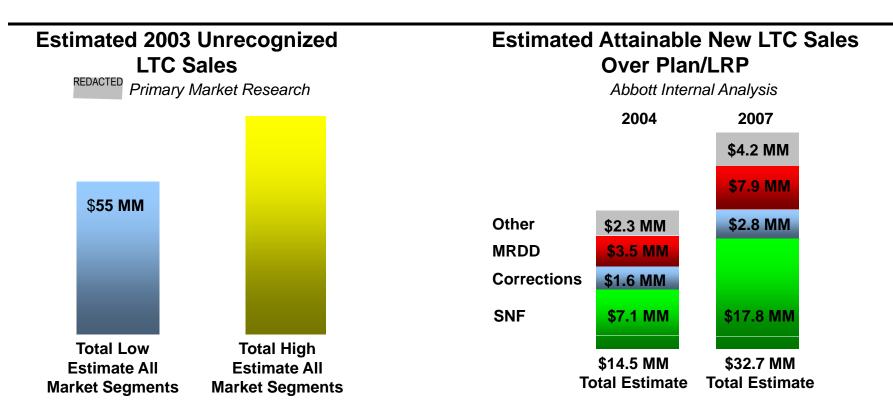
# Health Products Research Methodology and Results: Non-Retail Sales Force Optimization

Business Question: Is Depakote optimizing its non-field resources? If not, what is the profit maximizing number of reps and what accounts should they be targeting?



Business Answer: Current ISR reps are sufficient though call lists may need to be slightly readjusted. Current LTC reps are insufficient and should be increased by 24 reps, 1 RTS, 3 DMs, 1 RM and 7 RAMs.

## Refocused LTC sales and marketing efforts generates \$14.5 MM in new revenue in 2004 and \$105.8 MM in years 2005-2008.



#### **Factors Affecting Segment Growth Estimates**

Corrections	Low base, need to stem VPA growth
MRDD	Small patient base ,more fragmented LTCPP coverage
SNF	Higher current base , strong existing relationships

## A larger marketing organization will help increase Depakote's share of voice in LTC and create greater parity in Neuroscience.

#### **Proposed LTC Marketing Organization**



#### LTC Marketing Responsibilities by Channel Increases Efficiency & Effectiveness

- Disease knowledge
- Channel operations
- Channel specific CME planning and execution
- Channel specific meetings and events planning and execution

		Neuros	cience Promot	ional Resource	s		
	Mkt. FTEs	Promo \$'s	Net Revenue		Mkt. FTEs	Promo \$'s	Net Revenue
Psych '03	9	\$15 MM	\$350 MM	Neuro '03	4	\$10 MM	\$350 MM
LTC '03	1.5	\$2.6 MM	\$130 MM				
LTC Proposed	3.5	\$5.5 MM	\$150 MM				

## **Back-Up Slides Table of Contents**

- Market Understanding and Defining
- 2. Abbott's Past Performance in LTC
- 3. Market Sizing and Future Potential
- 4. Optimization Supports Need to Realize Incremental Sales
  - Sales Force Optimization
  - Marketing Expansion
  - Clinical Investments

## **LTC Market Complexities**

#### **Market Characteristics**

- Patients have greater incidence and prevalence of CNS disorders than the general population
- Degree of unmet medical needs in LTC increases physicians discretionary use of Rx products
- Heavy LTC Prescribers and influencers are usually low-decile writes in retail
- Government regulates initiation and continued use of Rx products in some LTC settings

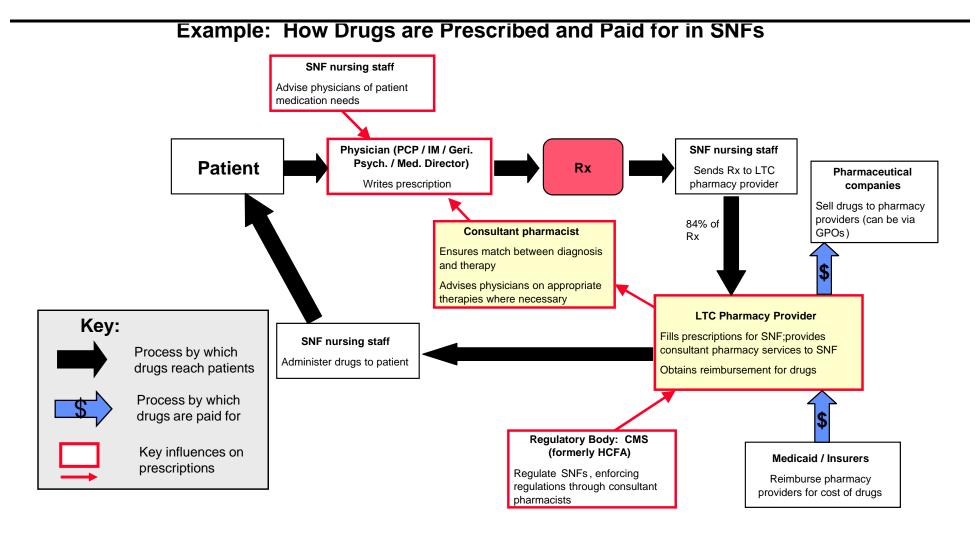
#### **Channel Characteristics**

- Long Term Care Pharmacy Providers (LTCPP) fill the majority of LTC Rxs
- LTCPP closed-door services are more involved and expensive than retail services, e.g. consultations
- LTCPP have contractual arrangements with manufacturers
- LTCPP measurements and metrics are much more limited than retail.
- LTC, as a percent of all pharmaceutical sales, has grown from 8% to 13% in the past five years

Long Term Care

Source: Abbott interviews, REDACTE , REDACTE

## Prescription fulfillment in all LTC settings in very complex.



Similarly complex process flows exist in other LTC setting segments.

Sources: Abbott Neuroscience LTC Business Review, REDACTED

## The LTC market is undergoing growth and change. Depakote LTC, while growing, lags the rest of the market.

#### Market Issues

- Pharmaceutical companies and LTCPP are expanding the LTC market
  - -The channel is estimated to offer 2 billion dollars in net sales in 2003
  - -Competitors are establishing contracts in other LTC settings, e.g. contracts in corrections
  - -LTCPP are expanding their reach to serve:
    - » ALFs
    - » MRDD institutions and group homes
    - » Corrections
- Product competition in the SNF segment of the LTC is intensifying
  - -Risperdal label change has caused prescribers and influencers to rethink medication choices
  - -Abilify is publishing LTC data and devoting sales resource to the channel
  - -Cholinesterase inhibitors have surpassed Depakote's LTC TRxs and have introduced behavior control data
  - -New Alzheimer's products will hit the market in 2004 (Memantine)
- Channel consolidation is accelerating
  - REDACTED acquired two other national Long Term Care Pharmacy Providers (LTCPP) in 2003 and

### **Depakote Issues**

- Depakote is the third or fourth medication choice behind antipsychotics for psychiatry needs in LTC
- Depakote is in a dead heat with other AEDs as a medication choice for addressing neurology needs in LTC
- Depakote has produced much less LTC data than its competitors
- Depakote has one of the smaller LTC sales force in the industry

## **Abbot's LTC History**

#### Where We've Been

- Neuroscience sales force launched in 1998 with 28 LTC Specialists and 1 National Account Manager (NAM)
- Launched clinical trials Elderly Mania - in hopes of obtaining an indication for treating aggression and agitation in the elderly
- Sales and marketing efforts 100% focused on treating elderly patients in skilled nursing facilities (SNFs)

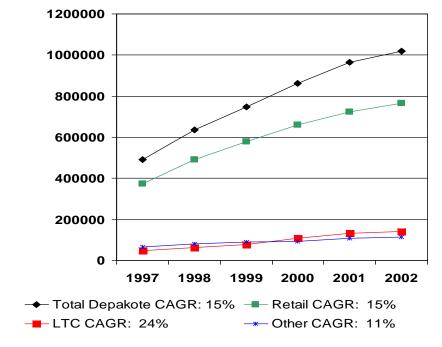
#### Where We Are

- Neuroscience sales force currently supports 55 LTC Specialists; 3 NAMs – last expansion took place in 2001
- Conducting retrospective analysis and investigator initiated studies to produce LTC data
- Sales and marketing efforts focused:
  - -75% SNFs
  - -15% MRDD
  - -10% ALFs and Other

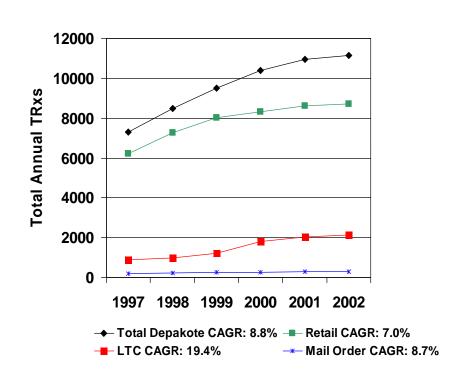
Source: Abbott interviews and historical documentation of channel efforts.

#### LTC's Past Contribution To Sales

## Depakote Gross Sales by Channel



#### **Total RXs**



## In LTC, Depakote faces the same product challenges as it faces in Psych and Neuro markets, plus unique facility based challenges.

## Depakote as Compared to Other Products Used in Select LTC Settings

	Efficacy	Safety	Tolerability	Overall Appeal
SNFs	+	+	+	+
				Lack of regulation concerns aids rating
ALFs	+	-	+	+
				Prescribers lack experience
MRDD Facilities	+	-	+	+
i aciiilles				Prescribers lack experience
Correctional	++	+	++	++
Facilities				Cost and broad spectrum utility aids rating

+++ = Superior rating or an attribute

+ = Average rating for an attribute

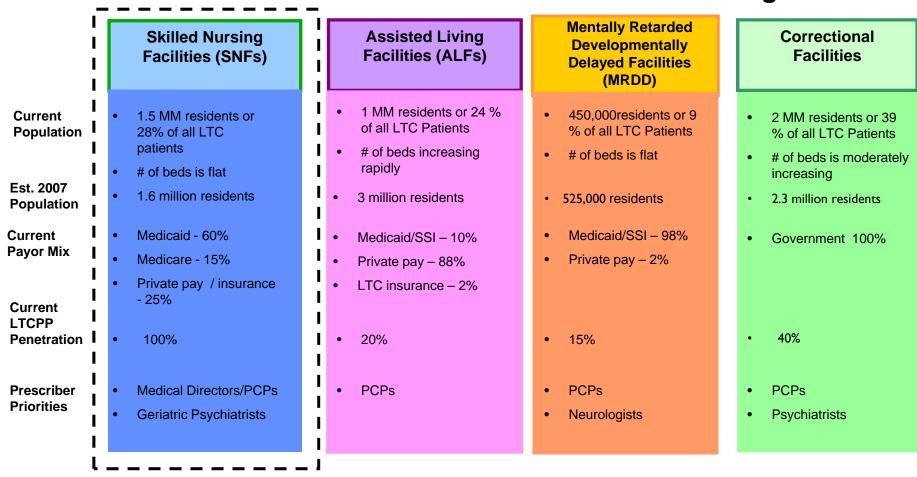
- = negative product attribute

--- = Highly negative product attribute

Source: Synthesized from REDACTED supplied primary data (QA).

### Neuroscience has redefined LTC to match the extended care market served by LTCPPs - aligning LTC's strategy with the larger brand strategy.

### 5 MM Total LTC Patients in Select LTC Settings



**Historic Abbott Market** Definition

REDACTED Sources: Abbott Primary Market Research. REDACTED NCAL Facts and Trends 2001; ALFA Overview of the Assisted Living Industry 2001;

Abbott Neuroscience Population estimates have been rounded. Business Review, National Center for Health Statistics, Health United States 2001

# Current LTC secondary data sources limit the ability to understand future sales activity and segment contributions.

Currently Available Secondary LTC Data	Current Data Elements	Limitations
Rx: NPA Provider Perspective ( -Buy In)	National accounting of Rxs for total     Sub Cat N1 – Nursing Home     Pharmacy Providers	<ul> <li>Lacks Rx by Sector</li> <li>Lacks Rx by Diagnosis</li> <li>Projects for REDACTED (which Abbott buys indecently)</li> </ul>
DDD \$( Sell Out)	<ul> <li>Depakote \$ for total N1s Nursing Home Pharmacy Providers</li> <li>Depakote \$'s by Outlet for total LTC</li> </ul>	<ul> <li>Lacks Depakote \$ by Sector - can not tie outlet dollars to facilities</li> <li>Lack Depakote \$ by Diagnosis</li> <li>Does not include REDACTED \$'s</li> <li>Can not tie Prescriber relationships to N1 outlets</li> <li>Can not define dollars by competitor (DDD groups competitors)</li> </ul>

#### **Unavailable But Useful Secondary LTC Data**

- Lists of MRDD facilities and the dollar volumes they carry
- Complete lists of correctional facilities and the dollar volumes they carry
- Complete lists of nursing home facilities and the dollar volumes they carry
- Complete doctor level data
- Mechanism for link doctor (or other provider / potential target) with facility and/or type of facility
- Dollars by competitor (DDD groups competitors)
- Dollars by competitor by facility type
- Any way to factor data by diagnosis
- Share of voice metric in LTC

# Abbott had to conduct primary market research to size the market's potential.

#### **Current LTC Data Limitations**

- Actual REDACTED account information only captures sales activity at the pharmacy outlet level.
- No publicly available data tracks sales activity from a pharmacy outlet to the facilities served by these outlets.
- Numerous REDACTED accounts currently categorized as "nursing home providers" are doing the majority of their business in other LTC settings.
- No publicly available LTC data source ties dollar sales to diagnoses in LTC.

The only way to precisely understand where today's Depakote LTC DDD dollar sales requires a unique account profiling exercise:

Each LTC rep would estimate the % of dollars directed to different facilities types affiliated with each outlet in their territory

We recommend pursuing this analysis over the next three months.

Note: Market research sample and methodology details are found in the appendix.

# LTC Primary Market Research May 2003: Design and Objectives

#### **Physician Sample**

Total Completed	# of Physicians Completing Study by Facility Type 248
Total Completed	240
Correctional Facility	49
PCP	4
Psychiatrist	45
MRDD	48
PCP	44
Neurologist	24
Assisted Living Facility	65
PCP	65
Skilled Nursin Facility	66
PCP	66

#### **Study Objectives**

- What is the size of the LTC market?
- What is the prevalence of Depakote's use in different LTC facilities across select neuroscience conditions?
- How is the Depakote brand currently being used in select LTC environments to treat select neuroscience related conditions?
- What can Abbott do to increase its usage?
- How much can the usage increase?

## **LTC Strategic Considerations**

## LTC Segment Evaluation Grid

LTC Market Segments	Financial Potential	Promotional Alignment	LTCPP's Ability to Impact Business	Competitive Advantages	Overall Segment Value to Abbott
Skilled Nursing					
Assisted Living					
MRDD					
Corrections					

Source: Abbott analysis.

## LTC Segments Financial Potential Analysis

### **Total Number of Residents Residing in LTC Facility Types**



LTC Residents with Select Neuroscience Conditions Receiving Rx Treatment



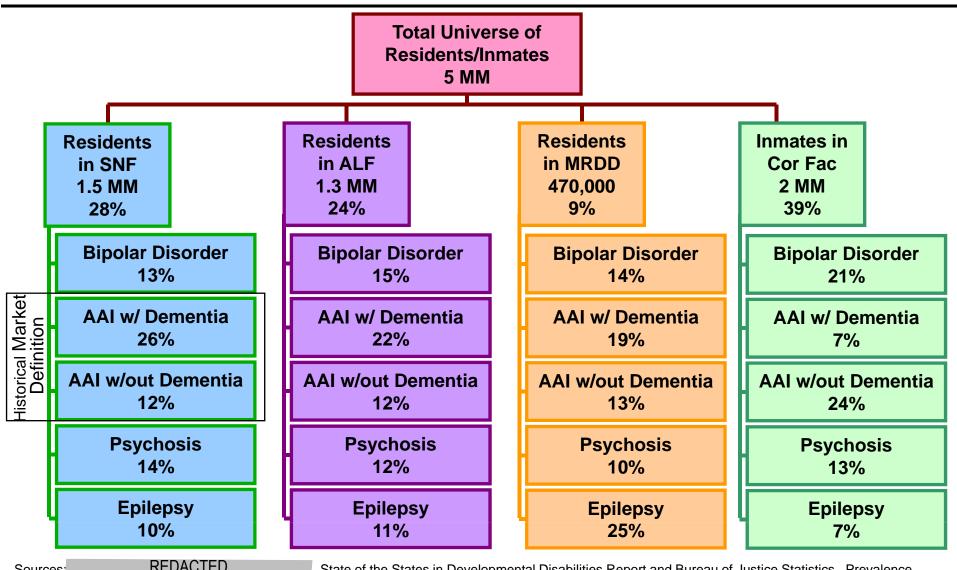
Total
Number of
Patients on
Each Brand

Average Daily Dose in MGs

Weighted X WAC Per MG X Length Of Therapy In Days

Medicaid and
Pharmacy
Provider
Rebates

### Resident Universe for LTC: Depakote Relevant Segments



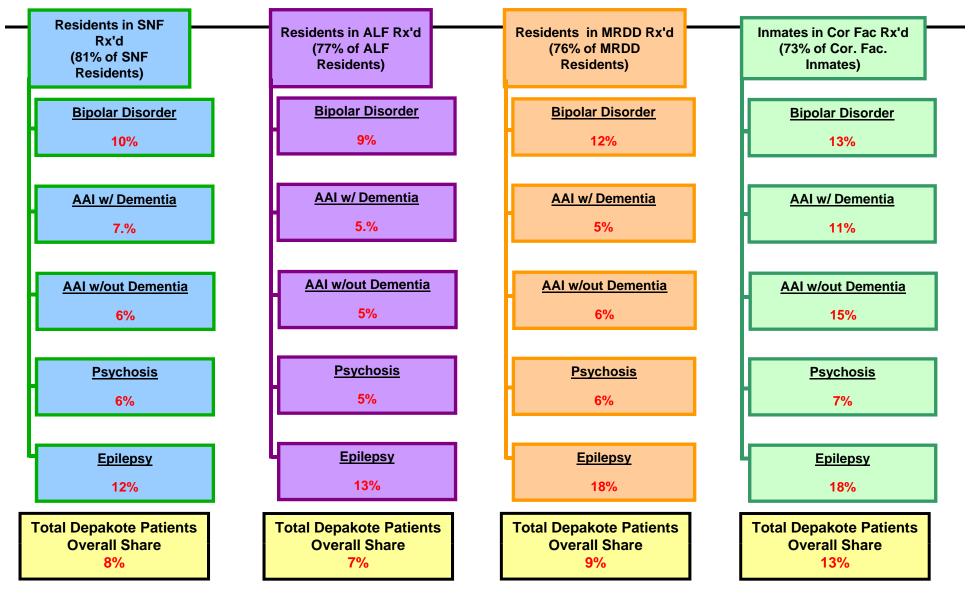
# Additional Prevalence Proof for Neuroscience Conditions in the LTC Marketplace

	SI	NF	A	LF	MR	DD	CO	RR
	2ndary Res	REDACTED	2ndary Res	REDACTED	2ndary Res	REDACTED	2ndary Res	REDACTED
Bipolar	10%(1)	13%		15%		17%	20% (6)	21%
AAI W/Dementia		26%		22%		15%		7%
AAI W/O Dementia		12%		12%		17%		24%
Psychosis	6% to 10% (2)	14%		12%		14%	10% (7) &(8)	13%
Epilepsy	6% (3) 8% to 15% (4)	10%		11%	14% to 24% (5) 45% to 67% (5)	25%		7%

### References for Secondary Prevalence Findings

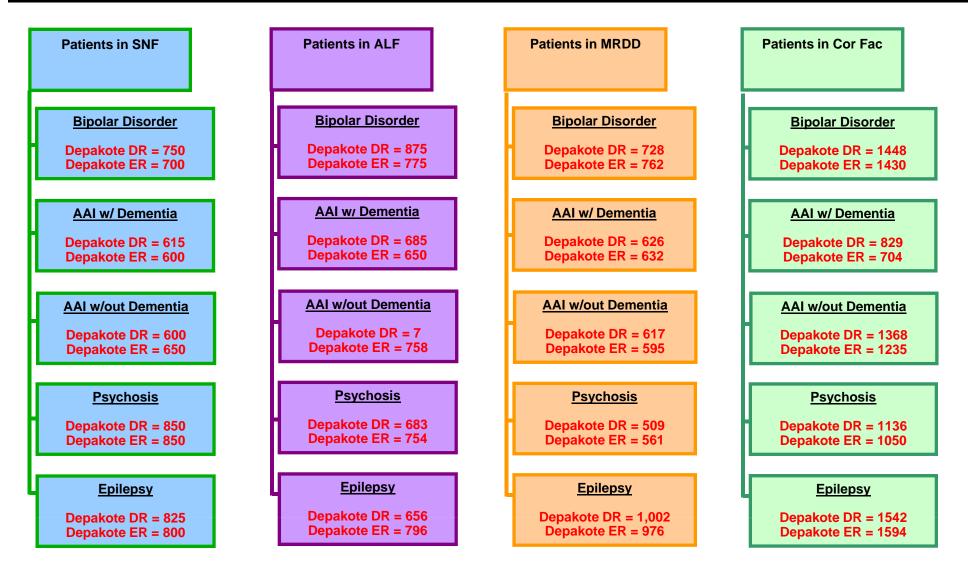
- 1 (A) 10% of Nursing Home patients have Bipolar disorder www.upcmd.com/dot/diseases/01076/disorder\_information.html
  - (B) Lifetime prevalence of Bipolar disorder in the general population has been underdiagnosed; incidence approaches 5% to 8% of the general population: Arnold L Lieber, MD: A Practitioner's Overview of the Soft Bipolar Spectrum:www.psycom.net/depression.central.lieber.html
- 2 Psychoses prevalence varies from 6% to 10% in the elderly population. Pietro Gareri, Conventional and Atypical Antipsychotics in the Elderly, Clinical Drug Investigation; www.medscape.com
- 3 Five or 6% of nursing home residents suffer from Epilepsy. K.L. Capozza Epilepsy Drugs Common in Nursing Homes: www.ahealthyadvantage.com/article/hscoutn/103437886
- Annual Incidence of Epilepsy by age: approximately 8% in 60-69 year olds; approximately 15% in 70-79 year olds; Robert W. Griffith, MD: Epilepsy is Quite Common in Old Age; www.healthandage.com/Home/gid2=734
- 5 14-24% of people with intellectual disability are affected by Epilepsy. 45-67% of people with severe intellectual disability are affected by Epilepsy. National Electronic Library for Health www.minervation.com/ld/healthservices/medical/3.html
- Prison populations have a four-fold incidence of Bipolar disorder compared to the epidemiology of the general population. (5% Bipolar disorder in general population (reference (1B) above) times 4 = 20%). GN Conacher, Management of the Mentally Disordered Offender in Prison.
- 7 600,000 to 1 million people iailed have a mental illness: 600000/2million inmates = 30% (combination of Bipolar and Psychosis in REDACTED data = 34%); National Council on Disability.
- 7% of sentenced men, 10% of men on remand and 14% of women in both categories were assessed as having a psychotic illness within the past year. REDACTED Severe Mental Illness in Prisoners.

### **Depakote's RX Share Summary By Condition**



Sources: Facility population counts provided by Abbott. Prevalence of condition data sourced from physician reported, REDACTED supplied primary data (QA).

## **Depakote Average Daily Dose (in mg) Summary**



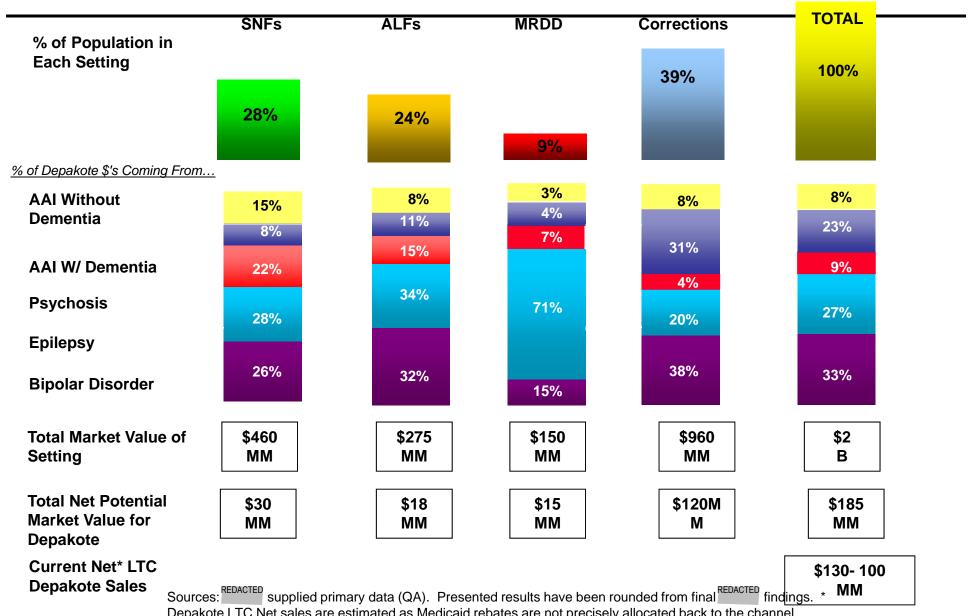
Sources: Facility population counts provided by Abbott. Prevalence of condition data sourced from REDACTED primary data (QA).

## Depakote Average Length of Therapy (Days Per Year) Summary

#### Residents in SNF Residents in ALF Residentts in MRDD Inmates in Cor Fac **Bipolar Disorder Bipolar Disorder Bipolar Disorder Bipolar Disorder** Depakote DR = 144 Depakote DR = 201 Depakote DR = 265 Depakote DR = 315 Depakote ER = 251 Depakote ER = 250 Depakote ER = 224 Depakote ER = 279 AAI w/ Dementia AAI w/ Dementia AAI w/ Dementia AAI w/ Dementia Depakote DR = 196 Depakote DR = 137 Depakote DR = 188 Depakote DR = 281 Depakote ER = 175 Depakote ER = 204 Depakote ER = 211 Depakote ER = 170 **AAI w/out Dementia AAI w/out Dementia AAI w/out Dementia** AAI w/out Dementia Depakote DR = 150 Depakote DR = 143 Depakote DR = 254 Depakote DR = 181 Depakote ER = 192 Depakote ER = 175 Depakote ER = 176 Depakote ER = 222 **Psychosis Psychosis Psychosis Psychosis** Depakote DR = 139 Depakote DR = 229 Depakote DR = 205 Depakote DR = 259 Depakote ER = 136 Depakote ER = 199 Depakote ER = 231 Depakote ER = 208 **Epilepsy Epilepsy** Epilepsy **Epilepsy** Depakote DR = 236 Depakote DR = 247 Depakote DR = 326 Depakote DR = 304 Depakote ER = 281 Depakote ER = 290 Depakote ER = 279 Depakote ER = 301

Source: Length of Therapy data sourced from PEDACTED primary data (Q7/9).

## Primary research suggested that potential Depakote LTC net sales could be \$55-\$85MM above current net sales.



# LTC is seeking to optimize corrections, SNF and MRDD sales and marketing efforts through 2008.

## LTC Segment Evaluation Grid

LTC Market Segment	Financial Potential	Promotional Alignment	LTCPP's Ability to Impact Business	Competitive Advantages	Overall Segment Value to Abbott
Skilled Nursing	Moderate \$25-30 MM annually	Moderate 54% Pl aligned	High	Moderate Antipsychotic regulations give slight advantage	High Represents core LTC business today.
Assisted Living	Moderate \$15-40 MM annually	Moderate 66% Pl aligned	Low	Low Antipshycotics and cholinestrate inhibitors dominate	LOW Growing segment but lacks LTCPP as key element in impacting business
MRDD	Low \$15-20 MM annually	High 86% PI aligned	Moderate	High Antipsychotic regulations give advantage	Moderate High strategic fit with Bipolar and Epilepsy.
Corrections	High \$120-135 MM annually	Moderate 60% PI aligned	Moderate	High  Cost advantages over antipsychotics	High High strategic fit with bipolar and epilepsy. Requires coordination with HIV.

Source: Abbott marketing analysis.

## LTC Strategy Execution Drivers

	Corrections	MRDD	SNFs
Depakote Eligible Patient Population	Y% or X MM inmates have conditions that could be treated with Depakote	Y% or X MM residents have conditions that could be treated with Depakote	Y% or X MM residents have conditions that could be treated with Depakote
# of Institutions	8,400 state, county and city jails and prison	7,100 large and small facilities	18,000 Nursing Homes 1.9 Million Beds
Depakote \$'s per patient, per year*	\$870 a year	\$485 a year	\$405 a year
LTCPP Coverage	Three national MCOs and their LTCPPs provide drugs to 30% of the market	National LTCPP consolidation is in its infancy	Four national LTCPP provide drugs to 35% of all SNF beds
Depakote Messages	Bipolar     Agitation &     Aggression	Epilepsy     Agitation &     Aggression	<ol> <li>Agitation &amp; Aggression</li> <li>Bipolar</li> <li>Epilepsey</li> </ol>
Promotional Mix ( In order of importance)	<ol> <li>CME</li> <li>RAM coverage</li> <li>Contracting</li> </ol>	<ol> <li>Sales rep coverage</li> <li>CME</li> </ol>	<ol> <li>NAM/RAM coverage</li> <li>Sales rep coverage</li> <li>CME</li> </ol>

Source: REDACTED primary market research conduct for Abbott Laboratories, May, 2003.

Note: Prevalence of disease states can be found in the appendix on page \_. Marketing plans by setting are found on pages \_ - \_ of the appendix.

## **LTC Optimization Supports**

Sales Force Optimization
Representative Increase
Management Increases
Key Supports

Marketing Expansion
Marketing Personnel
Marketing Budget
Contracting Expansion
Internal Support Needs

Clinical Data Expansion

Geriatric IIS

Corrections IIS

MRDD IIS

## **Competitive Field Sales Force Landscape**

	LIC	ISKS
REDACTED	80 FTEs*  160 FTE Hospital Reps- all 'Hospital' reps are 'Hospital and Long-Term Care' Reps and report through the same structure as the CNS reps.	
REDACTED	188 FTEs*  Elder Care: 4 Regional Directors, 28 DMs, 280 Reps  Long Term Care: 3 Regional Directors, 22 managers	Office/Institution: 58 DMs, 580 Reps. 16 Institutional account managers, 10 strategic account managers reporting through public sector & institutional business Director.
REDACTED	176 FTEs* 21 District Managers, 263 LTC Reps	13 District Managers, 118 ISRs
	7 DMs, 55 LTC Sales Representatives	9 ISR District Managers, 79 ISRs

<sup>\*</sup> Note: Total rep counts were reduced by 70% to account for time given to an atypical primary detail to arrive at an adjusted FTE count.

## **Abbott's Unique LTC Sales Focus**

### Targets shown are individuals - not accounts or institutions

#### **55 LTC Reps**

Account Management Sales flowing through LTCPP, including PCPs, Geri Psychs, Consultant Pharmacists and Nurses

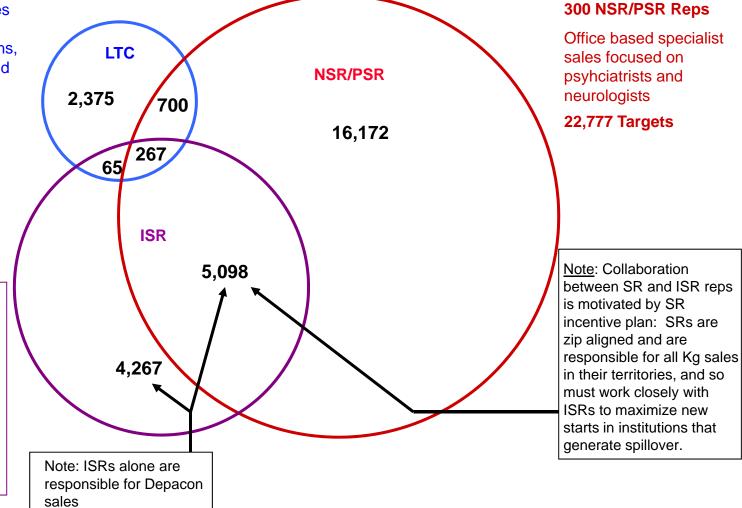
#### **3,407 Targets**

#### 79 ISR Reps

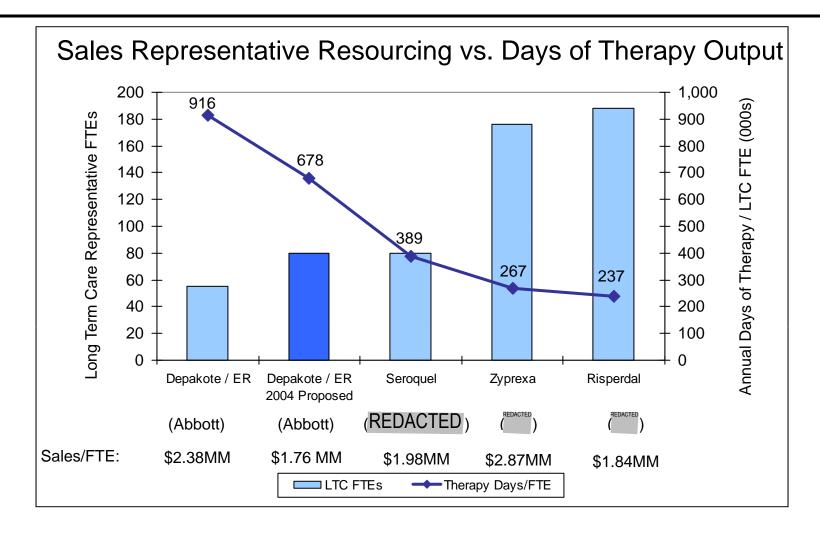
Institutional sales flowing through GPOs or IMS non nursing home providers

#### 9,697 Targets

Breakdown of Institution Hospital or Affiliated Clinic/Pharmacy	
Psych/MH Center or Affiliated Pharmacy	7%
CorrectiosI	4%
MRDD	2%
LTC Facility or LTCPP	2%
Other	9%



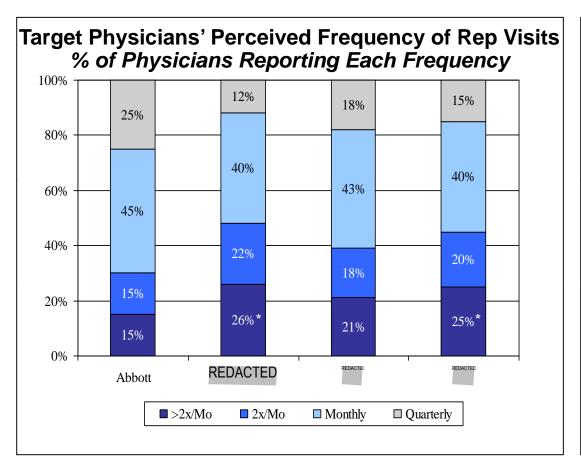
## Depakote LTC generates more days of therapy per rep than any major competitors.



Sources: REDACTED REDACTED Commercial Analysis and Marketing assumptions

Note: Depakote: 55 representatives, 100% of time on Depakote/Depakote ER = 55 FTEs. Zyprexa: 263 LTC reps spend 67% of time on Zyprexa = 176 FTEs Risperdal: 280 Elder Care reps spend 67% of time on Risperdal = 188 FTEs. Seroquel: 100 LTC reps spend 80% of time on Seroquel = 80 FTEs

## However, Abbott LTC Reps See Physician Customers Less Frequently than Competitor Representatives



### **Key Supporting Points**

- 16% of Abbott LTC targets surveyed indicated that Abbott reps could be *more valuable* by visiting more frequently
- One in five Abbott LTC *targets* are satisfied with Abbott reps
- One in ten Abbott LTC targets can't remember the last time they saw an Abbott rep

\*Denotes statistical significance relative to Abbott, p<=0.05 Source: REDACTED ABT (

ABT Custom Study, May 2003 Source:

# Recent History of LTC Sales Force Sizing Analyses and Recommendations

- <u>April 2001</u>: REDACTED recommends increasing LTC sales force from 54 representatives to 98 representatives
- March 2002: explores the concept of blending the ISR and LTC sales forces
- October 2002: REDACTED revises analysis, keeping LTC sales force separate from ISR sales force. REDACTED recommends expanding the LTC sales force to 80 representatives
- July-September 2003: conducts a promotional response analysis within Depakote's non-retails sale groups (ISRs and LTC)to arrive at the number of appropriate target counts, details need per account and number of reps need to address the most profitable targets.



# LTC Market: Sales Analysis

### **Overview**

### Objective

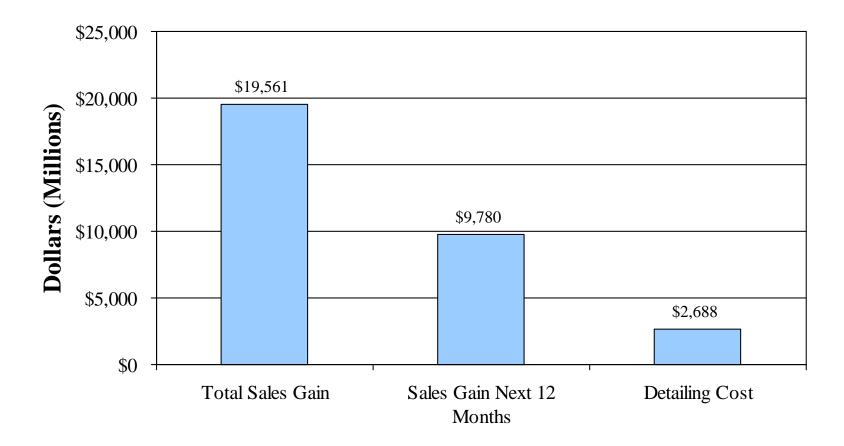
Calculate the incremental sales by increasing the LTC headcount by 16 reps,
 24 reps and 32 reps.

### Methodology

- In all scenarios, the following assumptions apply:
  - » Current Non-Targets are assumed to have already received 20% of their optimal frequency.
  - » LTC reps deliver 1,200 calls / year
  - » Call activity is reallocated away from unprofitable segments
- Note that, as with the original analysis, the optimal frequency for REDACTED outlets was capped at 2 times their historical LTC call level.
  - » This is due to the historical frequency being significantly below the Non-REDACTED outlets and that both REDACTED and Non-REDACTED outlets were used to derive the response curve.

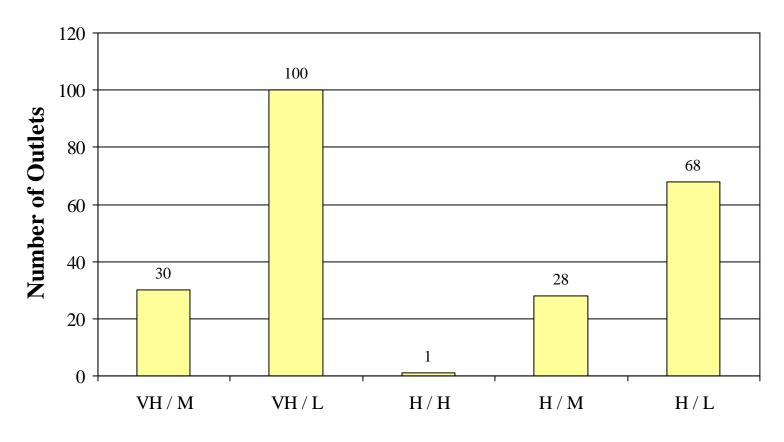
## LTC Analysis: Add 16 Incremental LTC Reps

The incremental sales gain over the next 12 months is \$9.8MM with a cost of \$2.7MM.



## **Outlets Added: Add 16 Incremental LTC Reps**

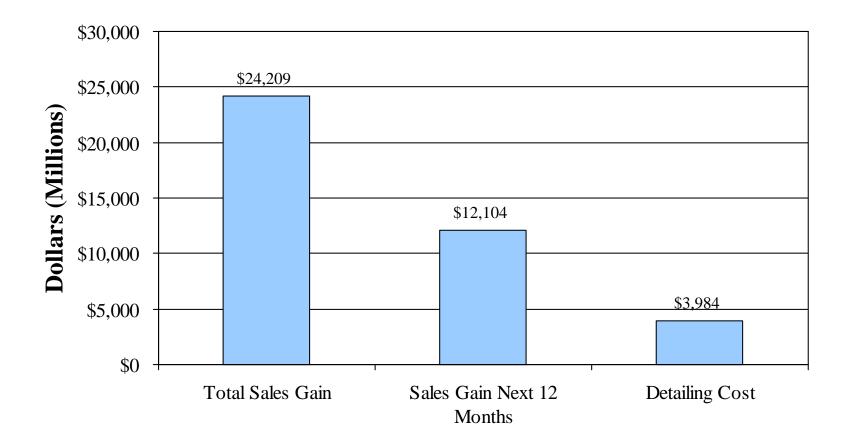
The added targets would be selected from the Current LTC Non-Targets.



**Current LTC Non-Targets** 

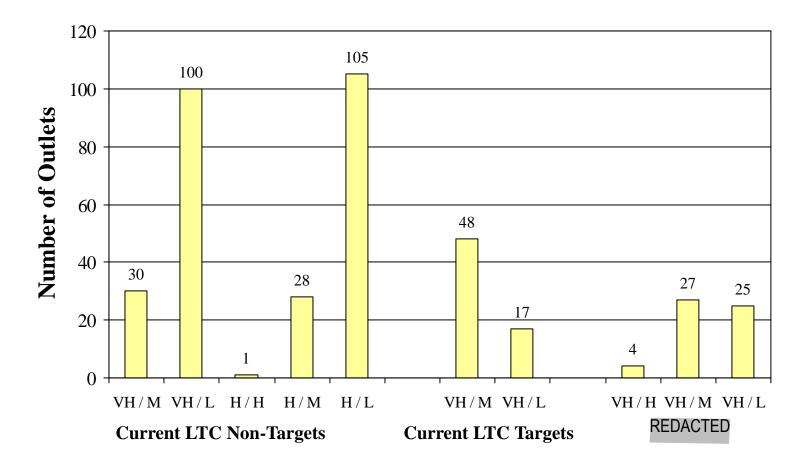
## LTC Analysis: Add 24 Incremental LTC Reps

The incremental sales gain over the next 12 months is \$12.1MM with a cost of \$4.0MM.



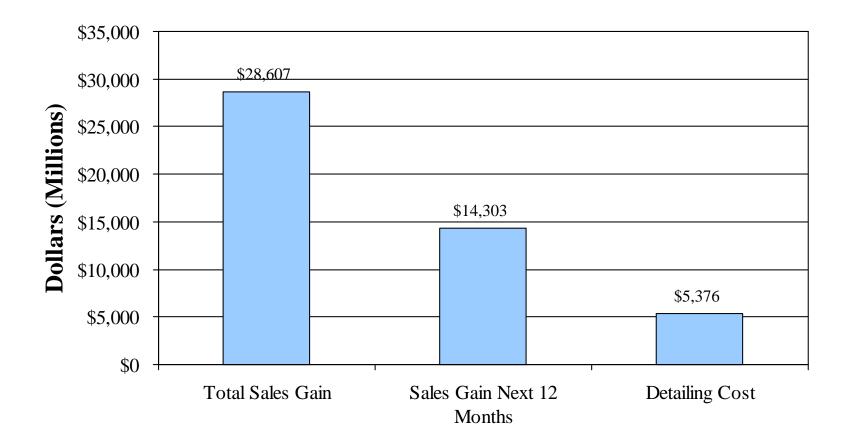
## **Outlets Added: Add 24 Incremental LTC Reps**

The added targets would be selected from the Current LTC Non-Targets, Current LTC Targets, and REDACTED outlets.



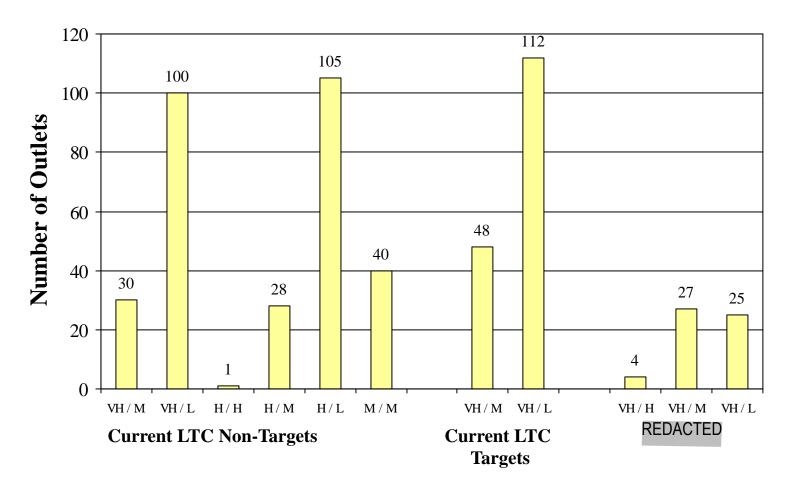
## LTC Analysis: Add 32 Incremental LTC Reps

The incremental sales gain over the next 12 months is \$14.3MM with a cost of \$5.4MM.

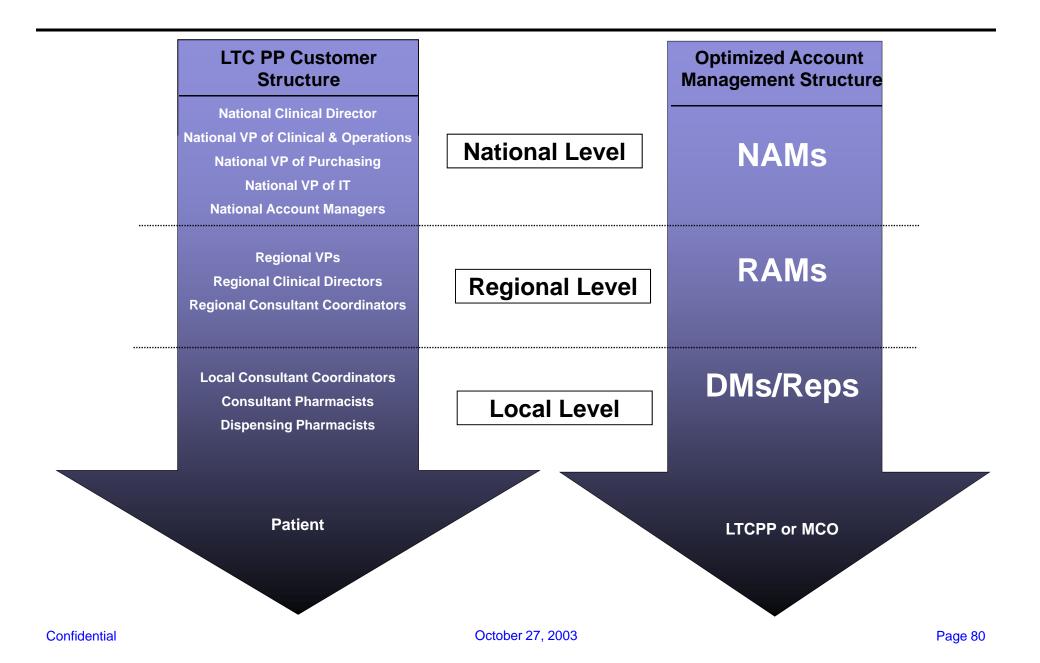


## **Outlets Added: Add 32 Incremental LTC Reps**

The added targets would be selected from the Current LTC Non-Targets, Current LTC Targets, and REDACTED outlets.



## **Proposed LTC Account Manager Optimization**



# Example of Western Area (AZ, CA, OR, WA) LTC RAM Responsibilities

### **National Pharmacy Accounts**

- REDACTED Regional Office
- 2 REDACTED Regional Clinical Coordinators
- REDACTED Regional Clinical Director
- REDACTED Regional VP (WA)
- REDACTED Consultant Coordinators (4)
- Regional Pharmacy Manager
   (CA)
- REDACTED Divisional Sr. Consultant
   (CA)

### **Independent Pharmacy Accounts**

- REDACTED Pharmacy (Van Nuys, CA)
- REDACTED Pharmacy (San Diego, CA)
- REDACTED Pharmacy (Portland, OR)

### **Nursing Home Chains**

- Regional DON REDACTED (CA)
- Regional Director REDACTED

### **Department of Corrections**

CA DOC System

Developmental Disability Nurse Association Chapters

CA and WA DDNA Chapters

### Other

REDACTED (In-patient psych – REDACTED supplies drug)

## Required LTC Representative Skill Set

#### Account Management Skills

- Account Planning Abilities
- Influence Mapping Expertise
- Needs Identification Skills
- Program Design and Delivery Skills

#### Personal Promotion Skills

- Integrity selling skills
- Objection handling abilities for both specialists and generalists

### Formulary/Reimbursement Knowledge and Understanding

- Medicaid Knowledge
- Medicare Knowledge
- Dually Eligible (Medicaid/Medicare)

### Market and Setting Knowledge and Understanding

- Demographic understanding of patient types
- Market drivers of business and medical needs
- Regulatory understanding

#### Product Understanding

- Bipolar Expertise (acute and maintenance)
- Epilepsy Expertise
- Agitation and Aggression Expertise
- Co morbid ConditionEexpertise

# LTC New Hire & Existing Filed Sales Representative '04 Training Plan

New Hire	ISTC	Post-ISTC
Hire for Jan 1, 2004 start date	Full Depakote certification	RFT training
Pre-ISTC assignments: Epilepsy, Migraine, Bipolar, MR/DD, DOC and SNF modules	New SNF Training*	LTC Mentor program (30, 90 and 120 days)
	New DOC Training*	Integrity Selling Follow-up teleconferences
	New MR/DD Training*	Field-Based Preceptorships
	Account-Based Selling	•
	Advanced Account-Based Selling*	
	Integrity Selling	
	ISTC -Based LTC Preceptiorship	
* Includes existing reps	· · · · · · · · · · · · · · · · · · ·	•

## Required LTC Field Sales Support: Data

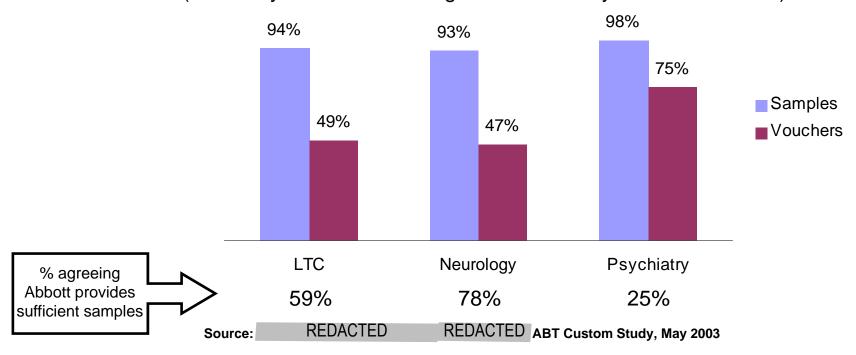
Data Set	Vendors	Business Uses	Annual Cost*
LTC Exponent	REDACTED	<ul> <li>Provide prescriber level data for a portion of the LTC market</li> </ul>	\$150,000
		Refine targeting	
		Refine Q & I requirements for LTC sales organization	
DNA MD View (Flat File)	REDACTED	Provide prescriber level data for a portion of the LTC market (largely REDACTED)	\$100,000
,		Refine targeting	
		Refine Q & I requirements for LTC sales organization	
Pharmacist,	Various	Provide facility identification data	\$ 50,000
and Facility Lists		<ul> <li>Provide organizational affiliations for key prescriber and influencers</li> </ul>	
		<ul> <li>Assist with direct marketing needs and event targeting</li> </ul>	

<sup>\*</sup> Annual costs account for both data acquisition and manipulation related charges should Abbott need to secure outside resources to fulfill programming and analysis needs.

## Required LTC Field Sales Support: Vouchers

### How Valuable are Samples/Vouchers to You and Your Patients?

(% of Physicians mentioning valuable or very valuable unaided)



### Based 2004 LTC per rep request on:

- -Abbott's 2003 SR and ISR experience
- -Competitive information
- Assumed that required vouchers will be funded through Depakote common funds.

## **LTC Optimization Supports**

Sales Force Optimization
Representative Increase
Management Increases
Key Supports

Marketing Expansion

Marketing Personnel

Marketing Budget

Contracting Expansion

Clinical Data Expansion

Corrections IIS

MRDD IIS

Agitation, Aggression IIS

# LTC marketing has developed setting and disease state positioning to ensure fulfillment of LTC's new strategy.

## Correctional Facilities

Mentally Retarded
Developmentally Delayed
Facilities (MRDD)

**Skilled Nursing Facilities (SNFs)** 

- Hold corrections only RCMs
- Tailor Stahl programming and DLNs to corrections
- Attend key corrections meetings
- Contract with corrections MCOs

- Hold MRDD only RCMs
- Enhance and expand MRDD Penry programming
- Deliver case-based special populations seizure treatment programming
- Develop targeted programming for reluctant geri-psychs
- Deliver value added prgms. for CPs and NPs w/ secondary clinical messages, e.g. nurses retention through better behavior mmgt.

### **Universal Institutional Positioning**

- Emphasize cost reduction and pharmacoeconomic messages based on evidenced based medicine in all settings
- Stress the advantages of Depakote ER over VPA and the utility of oral loading for acute treatment

#### **Bipolar LTC**

- Deliver core bipolar messages s to corrections, MRDD and SNFs
- Utilize CME to further address bipolar in the elderly or dually diagnosed patient
- Conduct IIS work with incarcerated or probationary bipolar populations

### **Epilepsy LTC**

- Deliver core seizure messages to corrections, MRDD and SNFs
- Utilize CME to address unique seizure types common among MRDD and elderly patients
- Conduct IIS work with specific institutionalized epilepsy populations

### **Agitation & Aggression LTC**

- Communicate symptom relevance from pivotal trials to prescribers
- Utilize CME to disseminate agitation research
- Utilize CME and advocacy ties to address care giver burden issues
- Conduct IIS work addressing common adjunctive therapy approaches - Casey LTC

## **Proposed 2004 LTC Promotional Budget Allocations**

Major Promotional Categories	Key Category Elements	'03 Actual Spend (000's)	2004 Propos Spend (000's	
Sales Force Support	Reprints, Sales Aids, and NAM War Chest	\$ 580	\$ 700	2 LTC sales aids, 2-4 slim jim like pieces and increased NAM war chest funds to cover corrections
Meetings and Events	Conventions, Meeting Symposia, Advisory Board	\$ 1.1	\$ 1.7	Reduced SNF meetings, additional Corrections and MRDD Meetings, 2 advisory meetings per market segment
CME Programs		\$ 400	\$ 1.0	"Key Pharmacoeconomic Concerns in the DOC: Why Branded is Better!", "Differential diagnosis: psychiatric and behavioral disturbances in the mentally retarded and developmentally delayed", "Increased Patient Compliance with QD Dosing."
Grants	Funds for institutes/3rd parties to support product research / foster general company goodwill	\$ 300	\$ 700	Added support to advocacy organizations to produce patient/care giver materials relevant to Corrections, MRDD and SNF environments.
Consultant Meetings	One on one meetings with key prescribers/influencers	\$ 0	\$ 675	4 corrections RCMs, 4 MRDD RCMS and 7 SNF DCMs
Agency Fees	PR and Advertising Fees	\$ 0	\$ 20	Use external PR support to publicize new findings
Market Research	Focus Groups, Studies	\$ 225	\$ 400	ATU and positioning research for new strategy
Data Purchases	Syndicated and proprietary data purchases	\$ 0	\$ 300	Annual LTC physician level data, new DNA product and list purchases for Corrections and MRDD
	TOTAL	\$ 2.6	\$ 5.5	

 $<sup>^{\</sup>ast}\,$  Full program details by sector are found in the appendix.

Confidential October 27, 2003 Page 88

# In corrections, the marketing team will carry out brand new programming for 2004.

	2004 Content Development Tactics for Corrections				
Care giver/Patient Education Materials (with or without an	Recognition and Appropriate Treatment of Bipolar Disorder/Behavioral Disorders in the Correctional Setting - to be done with National DOC association such as National Committee on Correctional Healthcare and separately with the major MCOs				
association tie in)	Understanding Bipolar Disorder and How if Affects You				
	Formulary Access reference sheets (once Depakote is on formulary for MCOs				
	Other spin-offs from CME programs				
CME Programs	Best Practices for Management of Bipolar Disorder/Behavior Disorders in the Correctional Setting: New Ideas and Practical Approaches, with Case Discussions				
	Seizures in the Correctional Setting: Environmental Triggers and Treatment Options				
	Key Pharmacoeconomic Concerns in the DOC: Why Branded is Better!				
	How Antipsychotic Overuse is Costing the DOC Time and Money!				
Market Research Studies	Positioning Research for the Correctional Setting				
	Message/Sales Aid Testing				
	Message Recall Study				
	ATU				
Investigator Initiated Study Topics/Data	Bipolar Disorder and Comorbid Behavior Conditions with or without Head Injuries				
Requirements	Efficacy of Depakote when Hepatitis C is present				
Training Needs	Getting to Know the DOC: Who are the Big Players? *MCO, *Pharmacy Providers, *Prescribers and Influencers,				
-	Understanding the Rx Cycle in the DOC: *Role of Formularies *Ultimate Decision Makers				
	Understanding the Corrections MArket				
	Key Pharmacoeconomic Concerns in the DOC: Why Branded is Better!				
	Deapkote corrections Data				
	Atypicals Corrections Data				

# In corrections, the marketing team will carry out brand new programming for 2004 (continued).

	2004 Meeting, Events and Pull Through Tactics for Corrections				
Advisory Board	1-2 National Advisory meetings (one to get a "smart" start out of the gate and one to reassess progress/direction at year-end)				
Meetings	4-8 Regional Advisory Meetings (competitive intelligence has suggested that much of this market functions on a Regional or Localized level. It is therefore necessary to cultivate Regional Advisors who could contribute to the success of this campaign. Two Advisory Meetings in each of 4 Regions would take place.)				
National Meeting	National Committee on Correctional Healthcare: 2 (Spring and Fall Meetings)				
Symposia	American Correctional Health Services Association: 2 (Spring and Fall Meetings)				
	American College of Forensic Psychiatry: 1 (Spring)				
Meeting Booth	5-6 "National" meetings, booth size medium if Depakote only; Large if coordinated with HIV				
Presence	National Committee on Correctional Healthcare: 2 (Spring and Fall Meetings)				
	American Correctional Health Services Association: 2 (Spring and Fall Meetings)				
	American College of Forensic Psychiatry: 1 (Spring)				
	14-15 Regional Meetings, booth size small if Depakote only; Medium if coordinated with HIV, Regional Meetings TBD				
Regional/District Consulting Meetings	4 Regional/District Consulting Meetings devoted to Corrections				
Sales Aid	2 molecule sales aids per year with relevant slim jims, dosing cards and flash cards				
Journal Ads	American Journal of Forensic Psychiatry (4-12);				
	Journal of Correctional Health Care (4-12)				
	CorrectCare (4; is a quarterly publication)				
Reprints	8-10 dissemination quality reprints				
Data Needs	List of MHC/Pharmacy providers servicing DOC: National and Regional				
	List of MDs servicing the DOC market by specialty and with Rxing patterns for Depakote and Competitors (similar to the old "PPP" report)				
	List of key support Organizations for the DOC				

Note: Promotional items would be cooled in the collection of the c

# The marketing team will increase its MRDD programming and tailor existing neurology materials.

	2004 Content Development Tactics for MRDD				
Care giver/Patient	"Did You Know" patient education pamphlets distributed to families regarding topics in epilepsy, psychiatric conditions and behavioral disturbance				
Education Materials (with or without an association tie in)	Depakote patient education pamphlets: what it is, what it is for, how it is dosed, side effects, etc.  Perhaps in association with ANCOR (American Network of Community Options and Resources) or AAMR (American Association on Mental Retardation)				
CME Programs	"Epilepsy in the mentally retarded / developmentally delayed"				
	"Differential diagnosis: psychiatric and behavioral disturbances in the mentally retarded and developmentally delayed"				
	"The role of anticonvulsants in the treatment of behavioral and psychiatric conditions in the mentally retarded / developmentally delayed population"				
	"Rationalizing treatment regimens for patients on multiple medications"				
	"The role of extended release medications in the treatment of the MRDD patient"  Some content development in association with DDRCs (Developmental Disability Research Centers)?				
Direct Marketing Programs	Journal subscription program: American Journal of Mental Retardation or Journal of Intellectual Disability Research				
	E-mail blasts featuring news on Depakote in the MRDD population				
Market Research Studies	Depakote ER conversion in MRDD facilities				
	Depakote/Depakote ER dosing in MRDD facilities				
	ATU for MRDD prescribers				
	Positioning statement testing: MRDD prescribers and caregivers				
	Sales Aid testing: if new campaign developed with new agency				
Investigator Initiated Study Topics/Data Requirements	"The use of divalproex in reducing frequency and severity of agitated / aggressive / impulsive behaviors in MRDD patients with or without seizures."				
Training Needs	General training on MRDD: patient types, caregiving environment, special issues in pharmacotherapy for the MRDD population: backgrounder and workshop (sales force)				
	Epilepsy in the MRDD population (sales force)				
	Behavioral disturbance and psychiatric diagnoses in the MRDD population (sales force)				

# The marketing team will increase its MRDD programming and tailor existing neurology materials (continued.

	2004 Meeting, Events and Pull Through Tactics for MRDD			
Advisory Board Meetings	2 annual advisory board meetings			
National Meeting Symposia	American Association on Mental Retardation (AAMR) Annual Meeting June 1-4, 2004 (Philadelphia, PA): "Enhancing Quality of Life for the Mentally Retarded and Developmentally Disabled"			
	Developmental Disabilities Nurses Association (DDNA) annual meeting April 24-26, 2004 (Charlotte, NC): "Identifying Seizures in the Developmentally Disabled"			
Meeting Booth Presence	Medium: American Association on Mental Retardation (AAMR) Annual Meeting June 1-4, 2004 (Philadelphia, PA)			
	Medium: Developmental Disabilities Nurses Association (DDNA) annual meeting April 24-26, 2004 (Charlotte, NC)			
Regional/District Consulting Meetings	4 Regional Consulting Meetings, 20-25 attendees each			
Sales Aid	2 molecule sales aids per year with relevant slim jims, dosing cards and flash cards			
Journal Ads	Journal of Intellectual Disability Research			
	American Journal of Mental Retardation			
	More mainstream journals as well: J Clin Psych, e.g.			
Reprints	4-6 dissemination quality reprints			
Data Needs	List of MRDD facilities with addresses and bed/patient counts			
	List of key prescribers in MRDD with addresses for targeting			
	Industry analyses: State of the States by David Braddock when updated			

Note: Promotional items would be coordinated with franchise wide activities. Pharmacy counting trays and formulary items would be the only unique LTC additions.

Confidential October 27, 2003 Page 92

# In 2004, SNF programming will be significantly revised and refocused on more intimate, higher ROI efforts.

	2004 Content Development Tactics for SNFs				
Care giver/Patient Education Materials (with or without an	Depakote patient education pamphlets: what it is, what it is for, how it is dosed, side effects, etc.				
	Alzheimer's disease education materials in association with Alzheimer's Association				
association tie in)	Caregiver guide				
	Value added talk: "Planting and Nurturing LTC physicians"				
CME Programs	"Differential diagnosis: psychiatric and behavioral disturbances in the elderly" – to include segment on diagnosing bipolar disorder in the older adult				
	"Rationalizing treatment regimens for patients on multiple medications"				
	"The role of extended release medications in the treatment of the elderly patient"				
	Treatment options for older adults with seizures				
	"Neuroprotective properties of divalproex"				
	Neuropsychiatric Issues in Long Term Care CME newsletter – several times a year, CME accredited (like Bipolar Disorder and Impulsive Spectrum Letter in psych) – rep distributed				
Direct Marketing Programs	E-mail blasts featuring news on Depakote in the elderly population				
Market Research	ATU for SNF prescribers				
Studies	Positioning statement testing: SNF prescribers and caregivers				
	Sales Aid testing: if new campaign developed with new agency				
	Identification of geri-psychs who do not view Depakote favorably; assessment of barriers to support and use				
Investigator Initiated Study Topics/Data Requirements	"The use of divalproex as adjunctive treatment in reducing frequency and severity of agitated / aggressive / impulsive behaviors in elderly patients with dementia."				
Training Needs	Advanced content training: Differentiating between bipolar disorder, secondary mania, and psychosis in the elderly (sales force)				
	Recognizing epilepsy in the elderly (sales force)				

# In 2004, SNF programming will be significantly revised and refocused on more intimate, higher ROI efforts (continued).

	2004 Meeting, Events and Pull Through Tactics for SNFs					
Advisory Board Meetings	2 annual advisory board meetings					
National Meeting	AMDA: March 4-7, Phoenix AZ. "Making the Desert Bloom: Creating Excellence in LTC Medicine"					
Symposia	ASCP: At least year-end; potentially mid-year as well Midyear is May 13-15, Scottsdale AZ "Geriatrics '04"					
	AAGP					
	US Geri Congress					
	NADONA or NCGNP					
Meeting Booth Presence	Large: AMDA					
	Large: ASCP					
	Large: AAGP					
	Large: US Geri Congress					
	Medium: NADONA or GNP					
Regional/District Consulting Meetings	7-14 District Consulting Meetings, 20-25 attendees each					
Sales Aid	2 molecule sales aids per year with relevant slim jims, dosing cards and flash cards					
Reprints	6-8 dissemination quality reprints					
Journal Ads	American Journal of Geriatric Psychiatry					
	More mainstream journals as well: J Clin Psych, e.g.					
Data Needs	Prescriber-level data for all 50 states					
	Facility utilization data for account-based targeting					

Note: Promotional items would be coordinated with franchise wide activities. Pharmacy counting trays and formulary items would be the only unique LTC additions.

# Competitor's Current Contracting Includes Corrections and SNF focused LTCPP's.



Confidential October 27, 2003 Page 95

# Contracting with dominant LTC pharmacy providers has been an effective tool for competing in the LTC market.

## Zyprexa (REDACTED) & Risperdal (REDACTED)

### **Contract Driver: Maintaining market share**

- "'s and s contracts with LTC pharmacy providers give rebates for maintaining market share for Risperdal and Zyprexa within the atypical market basket
- These contracts do not place Depakote in direct competition with atypicals
- These contracts are moderately easy to fulfill
  - Many providers earned several million dollars in rebates last year
  - Abbott's review of the 2002 REDACTED data which we purchase suggests that:
    - » Risperdal received \$4 million in rebates on nearly \$40 million in sales to REDACTED
    - » Zyprexa received \$3 million in rebates on \$60 million in sales to REDACTED

#### **Depakote**

#### **Contract Driver: Net kilogram growth**

- Abbott contracts with LTC pharmacy providers give rebates for growing kilogram sales
  - Abbott's current contractees provide pharmacy services for about 54% of SNF beds
- Contracts also oblige pharmacy providers to participate in Abbott's pull-through programs
  - Medical education on appropriate use of Depakote
- Contract structure was altered this year to make contracts more competitive
  - Earlier contracts required 10% kg growth for 2% rebate and were so difficult to fulfill that LTCPPs did not bother trying
  - Competitive contracts required as a loss-avoidance mechanism:
    - e.g. REDACTED (now owned by REDACTED) instituted a therapeutic interchange program replacing Depakote with generic valproic acid, losing Abbott 24% of its Depakote business; competitive contracts necessary to avoid a repeat occurrence
  - Under new contract terms, most contractees have driven double-digit kilogram growth in 2002 vs. 2001 and are driving ER conversion

## **Select Contracting Will Further Solidify Influence in LTC**

Care	LTCPP	Orgs	Recom-	Rationale		
Setting	Type	(Beds)	mendation	+	-	
Skilled Nursing Facilities	Very Large National or Regional LTCPPs	5 (0.81MM)	Continue contracting	<ul> <li>Large numbers of beds tightly controlled by few organizations</li> <li>Demonstrated performance on Abbott contracts</li> <li>High strategic fit</li> <li>High barriers to exit</li> </ul>	Moderate \$\$ opportunity/bed	
	Mid-Sized Independent Pharmacy Providers	6 (42 K)	Do not contract	<ul> <li>Have consultant pharmacists / processes through which to control drug usage</li> <li>Contracting experience with atypicals</li> </ul>	<ul> <li>Moderate \$\$ opportunity/bed</li> <li>Moderate number of beds</li> <li>Moderate to low probability of profitability</li> <li>Likely acquisition candidates</li> </ul>	
Corrections	Large LTCPP or MCOs focused on corrections	3 (0.6 MM)	Initiate contracting	<ul> <li>Large numbers of beds tightly controlled by few organizations</li> <li>High \$ opportunity/bed</li> <li>High probability of profitability</li> <li>High strategic fit</li> <li>Synergies with HIV franchise</li> <li>No Medicaid</li> </ul>	Conversion to VPA already underway	
MRDD	Very Large National or Regional LTCPPs	5 ( 50 K)	Continue contracting	<ul><li>Same as above</li><li>High \$ Opportunity/bed</li></ul>		
	Independent PPs focusing on MRDD	5 (12K)	Do not contract	High opportunity per bed	<ul><li>Few beds / fragmented</li><li>No consultants / poor control</li></ul>	

Confidential Source: Abbott marketing analysis.

# Incremental sales exceed rebates paid under current Depakote LTC contracts...

	Adj Sales Growth 1Q01-1Q02	Incremental Sales	Contract Rebates	Adj Sales Growth 4Q01-4Q02	Incremental Sales	Contract Rebates
REDACTED	12.8%	\$955,192	\$394,185	17.5%	\$1,401,927	\$508,544
REDACTED	18.8%	\$521,444	\$216,023	16.9%	\$545,656	\$204,674
REDACTED	15.3%	\$420,345	\$172,933	13.6%	\$422,192	\$151,477
REDACTED	35.1%	\$245,342	\$98,121	25.1%	\$217,765	\$82,139
REDACTED	-6.0%	(\$50,266)	\$0	6.8%	\$53,987	\$0
REDACTED	28.3%	\$143,853	\$58,093	27.7%	\$180,164	\$67,405

### Over time, contracts appear to have become more efficient on the top line:

In 1Q02, Abbott paid an average of \$0.42 for each incremental sales dollar

In 4Q02, Abbott paid an average of \$0.36 for each incremental sales dollar

# ...But what is the true incremental value of further expanded contracting, relative to the alternative?

### **Analytic Exercise: Key Steps**

- Gather data from contractees (test group)
  - Where possible, dissect test group by bed type (test the hypothesis that in some facility types growth is easier to drive)
- Gather data from non-contractees (control group), by bed type where possible
- Compare growth rates for test vs. control group (topline opportunity)
- Compare profitability of test group vs. control group under a contract (pricing assistance)
- Summarize financial opportunity: incremental value of contracting
- Evaluate key non-financial criteria (control, data capabilities, etc.)

## **Incremental Value of Contracting: Analysis**

Example: Skilled Nursing and Assisted Living (Blended)

"Test Group" Subset of current contractees				
<u>Organization</u>	<u>Beds</u>			
REDACTED	198,000			
REDACTED _ REDACTED	24,000			
REDACTED _ REDACTED	9,100			
Source: REDACTED and REDACTED internal records.				

"Control Group" Subset of potential contractees	
<u>Organization</u>	<u>Beds</u>
REDACTED	7,000
REDACTED	4,200
REDACTED	12,600
REDACTED	1,350
Source: Providers through third-par	tv ( <sup>REDACTED</sup> survev.

## **Incremental Value of Contracting: Analysis**

### Example. Skilled Nursing and Assisted Living (Blended)

Historical: Adjusted Sales Growth per Bed

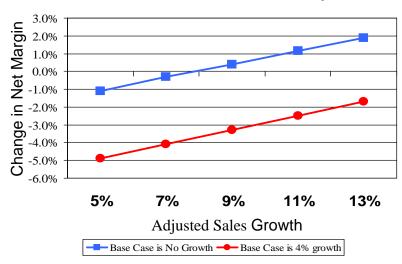
9%

No data
available
01-02

Contracted

Non-Contracted

New Contract: Sales Growth vs. Profitability\*



- Analysis suggests that if modest growth is occurring without a contract in these SNFs/ALFs, the short-term risk/reward ratio of a contract may be unfavorable.
- A conservative estimate that the regional contractee could achieve half the incremental growth of a national contractee places the expected growth rates under a contract between 7% and 9%, which is only profitable if little to no base case growth is assumed.
- Profitability may be somewhat understated here, however, if ER conversion could be driven higher than the assumed 20% under a contract scenario.

<sup>\*</sup> Assumes that contract drives ER% from 12.5% to 20% (benchmark: REDACTED 18.5%) and that Medicaid % of business = 60%

## **Incremental Value of Contracting: Comment**

### MRDD and Corrections Focused Pharmacies

- Data are limited for both "test" and "control" groups for MRDD facilities and correctional facilities.
   However, assessments may still be made:
- MRDD-Focused Pharmacies:
  - REDACTED (just 421 beds), focusing on MRDD:
    - Kg growth of 9.6% for Q103, over same quarter last year
    - ER% climbed to 25%
  - Preliminary data suggests that for non-contracted accounts, adjusted Depakote use is flat or declining in this market.
  - However, market is too fragmented to make contracting a viable approach
- Correctional facilities:
  - There are no bed-adjusted data on contracted correctional facility beds
  - Preliminary data suggest that for non-contracted accounts, Depakote use is flat or declining in these markets.
    - Taken together, REDACTED, REDACTED (REDACTED) and showed flat Depakote sales (not price adjusted)
    - Limited data on selected smaller non-contractees suggest that Depakote use is declining in their correctional facilities.

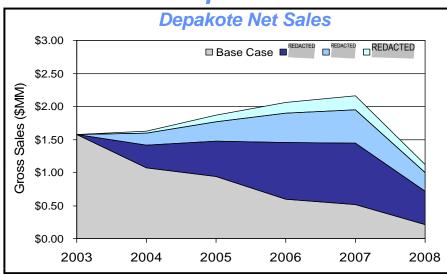
# Department of Corrections Contracting Makes Sound Economic Sense for Abbott

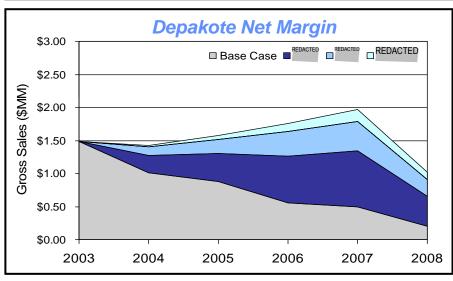
### Corrections Contracting Initiation Rational

- DOC lives are valuable to Abbott
  - Dollar value per inmate treated is 2x that of treated SNF residents
  - No Medicaid → high level of profitability
  - Great potential for ER penetration due to med pass reduction
- Current DOC business is at risk
  - Major corrections MCOs have begun converting Depakote business to VPA MATTY Q203 vs.
     MATLY, VPA purchases grew at 16 times the rate of Depakote/Depakote ER purchases
- Contracting with 3 major Corrections MCOs and their Pharmacies is a low-cost, low-risk guaranteed return tactic
  - Contracting with 3 managed care organizations captures over 30% of 2.1 million (est.) DOC lives
     ( REDACTED , REDACTED )
  - HIV is already pursuing contracts with these same three MCOs
  - No additional account management heads are required but additional pull through must be provided by reps
  - Rebate payment is margin positive in every scenario
    - 2004 incremental revenue \$0.5 MM in 3 accounts
    - 2005-2008 incremental revenue \$5.0 MM in 3 accts
  - Contracting can be further supported by psychotropic appropriate use programming similar to what is currently being done in the state of Massachusetts

## **Corrections: Expected Case with Contracting**

## A contract in combination with an AU program will turn around Depakote declines in these three key accounts.



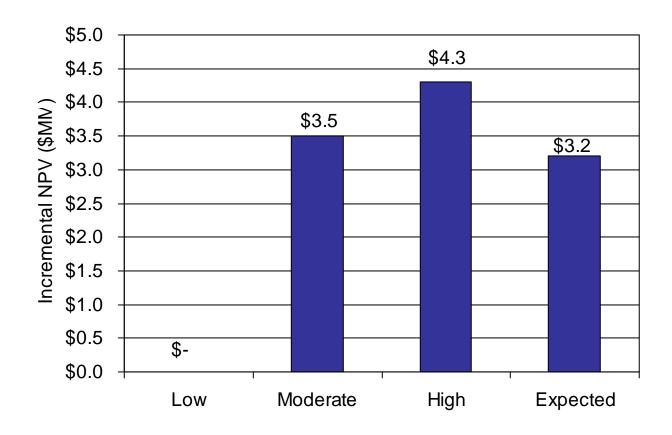


#### Rationale / Assumptions

- Interviews indicate interest in reducing use of expensive atypicals, particularly Zyprexa
- Combining education with contract rebates will make it more palatable to switch to Depakote and Depakote ER. rather than VPA
  - Switching from Zyprexa to Depakote ER where appropriate could save accounts approximately \$7 per patient per day, estimated to be over \$5 million between these three accounts.
- Recent examples of effective two-pronged strategies:
  - of Kansas City: Overall AIF Rxs declined 10%, while Biaxin market share and volume increased.
  - REDACTED of Appleton, WI: Biaxin share grew from 3.8% prior to program launch (4Q97) to 9.3% at the end of the year of launch and 15.2% one year later. Volume more than doubled during this time.
- s generic valproate product may dampen the effects of a contract, but will not preclude growth (as in Cenestin / Premarin case, discussed on p.11)
- Assumes purchasers for the DOC will continue to pay WAC for Depakote and Depakote ER
- Assumes Medicaid will not become a factor in the DOC market in the forecast period

## **Corrections: Expected Case with Contracting**

# Contracting in the DOC NPV is \$3.2 MM through 2008 Relative to Base Case



## **LTC Optimization Resource Needs**

Sales Force Optimization
Representative Increase
Management Increases
Key Supports

Marketing Expansion
Marketing Personnel
Marketing Budget
Contracting Expansion
Internal Support Needs

Clinical Data Expansion

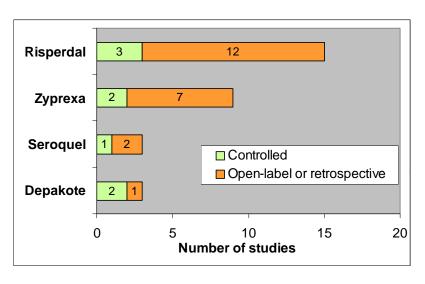
Geriatric IIS

Corrections IIS

MRDD IIS

# In SNFs alone, atypicals have much more clinical data than Depakote – especially open label and retrospective studies.

#### Published dementia studies since 1996



- This includes all studies for which abstracts are available on Medline or selected databases, except studies of single cases
  - May include studies that were not sponsored by pharmaceutical companies
  - Each study is counted only once, even if multiple publications have resulted
- Controlled studies: blinded and randomized, vs. placebo or comparator
- Open-label / Retrospective studies: includes chart reviews

#### **Details of controlled studies:**

### Risperdal studies

- n=625 & n=344 vs. placebo; n=58 vs. Haldol
- Endpoints: psychiatric and behavioral symptoms; extrapyramidal side-effects

### Zyprexa studies

- n=137 & n=206 vs. placebo
- Endpoints: symptoms of agitation and psychosis

### Seroquel study

- n=378 vs. placebo and Haldol
- Endpoints: symptoms of agitation and psychosis; tolerability

#### Depakote studies

- n=172 vs. placebo, discontinued (M97-738); n=56 vs. placebo
- Endpoints: symptoms of mania (M97-738);
   symptoms of agitation (both studies)

Sources: Confidential

REDACTED

REDACTED

REDACTED

# KOLs advise that clinical data specific to each Sector is needed to best impact Depakote business in the DOC and MRDD Markets.

#### For the DOC Sector :

- The DOC represents a unique group of patients with biological and environmental issues contributing to patient condition
- Pharmacological treatment decisions for DOC patients can be different than for those in the general population:
  - » Severity of condition can be greater in the DOC environment
  - » Patient compliance can be more problematic
  - » Consequences of treatment failures more severe
- Studies in the DOC patient population most relevant to practitioners

#### For the MRDD Sector:

- The MRDD patient population is unique and represents a group that can have severe handicaps
- Identification and appropriate classification of patient conditions is problematic due to the patient's inability to articulate symptoms
- Pharmacologic treatment decisions for MRDD patients can be different due to the nature of the patient's condition

# **Qualitative Opinion Leader Interviews: Assessment of Depakote Study Needs in Correctional and MRDD Settings**

#### Interviews Completed as of 8/19/03:

- Corrections Experts:
  - DR REDACTED
  - DR. REDACTED
  - DR. REDACTED
    REDACTED
    REDACTED
  - DR. REDACTED
- MRDD Experts:
  - DR REDACTED
  - DR. REDACTED
  - REDACTED , Rph (Chief of REDACTED MRDD program in Illinois, 5000+ beds)
  - REDACTED , RN (Co-Chief of REDACTED MRDD program in Illinois, 5000+ beds)

## Influence Clinical Data Would Have on Prescribing Choices:

- Respondents rated the influence of clinical data as a 9 on a ten-point scale (n=6)
  - "On a ten point scale where 10 means extremely influencial to my prescribing choices and 1 means not at all influencial to my prescribing choices, how would you rate clinical data in terms of its influence?"
- Respondents cited peer and Opinion Leader recommendations, articles in peer reviewed journals, and quality CME programs as preferred vehicles to access product information.

## **Proposed IIS LTC Study Descriptions in Correctional Facilities**

#### Conditions Assessed:

- Agitated/Aggressive/Impulsive behaviors with or without head injuries
- (per REDACTED) Bipolar Disorder with at least one comorbidity (have a laundry list that could include:
  - » Agitated/Aggressive/Impulsive behaviors
  - » MRDD
  - » head injury
  - » substance abuse
  - » ADHD
  - Others (DR. REDACTED noted that the design could resemble the abulatory study she is currently doing for Psychiatry Team)

#### Type of Study:

 Prospective (Note: Informed consent requirements and advocacy oversight may require that any prospective study use two active agents.)

#### Study Setting:

- Jails
- Prisons
- Probation catchment (DR REDACTED suggested that if getting IRB approved for prison population is a problem, it
  would be possible to screen probation patients or patients with a prison/jail record)

#### Primary Assessment:

- Efficacy
  - » Improvement in Bipolar
  - » Decreased frequency and severity of behaviors; patients "less triggered" by stressors
  - » Decreased frequency and severity of comorbid condition
- Also measure side effects, safety, tolerability

# Proposed IIS LTC Study Descriptions in Correctional Facilities (continued)

#### Primary endpoints:

- YMRS
- Overt Aggression Scale and others
- Staff keeps log of frequency of behaviors; measure Vs. staff assessment
  - » Use of restraints
  - » Time in isolation or solitary confinement
  - » Number of medication passes required
- Seizure measurement scales
- Other scales relevant to comorbid conditions.
- Cost savings due to better compliance, fewer side effects, fewer relapses etc

### Time period for study:

- Jails: 4 week study
- Prisons: 4 week study (but could be longer due to inmate length of stay)
- Probation: 8 week study

#### Patient Inclusion Criteria:

See primary assessment

#### Treatment Arms:

- Depakote ER vs placebo or Loading dose Depakote ER vs. Non-Loading Dose DepakoteER (per DR. REDACTED)
- Depakote ER Vs. valproic acid
- Depakote ER Vs. an antipsychotic (Zyprexa: could show results and differences in side effect profiles)

## **Proposed IIS LTC Clinical Study Descriptions in MRDD**

#### Conditions assessed:

Agitated/Aggressive/Impulsive behaviors with or without seizures

#### Type of Study:

- Prospective (per MD respondents)
- Retrospective ok (per REDACTED pharmacist)

#### Primary Assessment:

- Efficacy
  - » decrease frequency and severity of behaviors; patients "less triggered" by stressors
  - » decrease frequency and severity of seizures

#### Primary endpoints:

- Overt Aggression Scale and others
- Staff keeps log of frequency of behaviors; measure Vs. staff assessment
- Seizure measurement scales

#### Time period for study:

 3-6 months (it was noted that there is a seasonal response: patients have more behavioral problems in the Spring/Summer versus Fall/Winter. Therefore a study of 1 yr... or more would eliminate the seasonality)

#### Patient Inclusion Criteria:

- Patients are required to have failed behavioral therapy or behavioral therapy must have been ruled out as an option in order to begin pharmacotherapy.
- It was also suggested that patients could be those who previously failed treatment on a low dose of an antipsychotic

#### Treatment Arms:

- Depakote ER Vs. behavioral therapy (double blind)
- Depakote ER Vs. an antipsychotic (Zyprexa: could show results and differences in side effect profiles)
- AP therapy Vs. AP plus Depakote ER
- Depakote ER Vs. another AED

# KOLs also advise that the best development path for Depakote in elderly agitation would be adjunctive studies with atypicals.

- Two major clinical studies of Depakote monotherapy were discontinued, for reasons unrelated to efficacy:
  - M97-738: Depakote in Elderly Mania Showed efficacy<sup>1</sup>, but discontinued in 1999 because of excessive somnolence
    - » Somnolence was caused by dosing schedule that was too aggressive for an elderly population
  - M99-082: Behavioral Agitation in Elderly patients with Dementia Discontinued in 2001 before any results were available, because recruitment targets could not be met at reasonable cost
    - » Recruitment was very slow because inclusion criteria were too restrictive: in particular, patients on antidepressants were excluded, thus reducing the eligible population by around 50%
- Key opinion leaders therefore advise an adjunctive study as the best development path for Depakote in BDD:
  - Investigators unlikely to be willing to conduct further Depakote monotherapy trials, because of prior experiences
  - The adjunctive market is large: Geriatric psychiatry advisors estimate 50-70% of patients require polypharmacy for management of aggression
  - Adjunctive Depakote works: Existing data<sup>2</sup> shows that Depakote + atypical combination is effective in patients unresponsive to monotherapy or taking multiple atypicals
  - Recruitment will be easier: The majority of BDD patients are already treated with antipsychotics, so the eligible population will be large
  - Drop-outs due to adverse events can be minimized: Availability of ER 250 mg and a better understanding of tolerability issues in the elderly means the side-effects caused M97-738 to be discontinued can be avoided

Sources: (1) Tariot *et al.*, Curr. Therapeutic Res. 2001, 62: 51-67; (2) Narayan & Nelson, J. Clin. Psychiatry, 1997, 58: 351-4; M99-082 Study protocol; Draft FDA submission prepared by Abbott proposing label change to Depakote for indication in elderly agitation; Neuroscience clinical team, strategic review document

## **Proposed IIS LTC Clinical Study Descriptions in Elderly Agitation**

#### Conditions assessed:

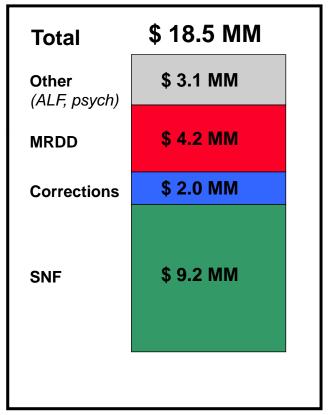
- Agitated/Aggressive/Impulsive behaviors with or without seizures
- Type of Study:
  - Prospective open label
- Primary Assessment:
  - Efficacy as measured by the PANSS Excited Component, which includes measurement of the following:
    - » impulse control
    - » tension
    - » hostility
    - » degree of cooperativeness
    - » excitement
- Primary endpoints:
  - PANSS Excited Component
- Time period for study:
  - 12 months
- Patient Inclusion Criteria:
  - Probable or possible Alzheimer's
  - Probable or possible vascular dementia
- Treatment Arms:
  - Depakote ER and atypical, vs. atypical + atypical , vs. atypical alone; n=30-40 each group

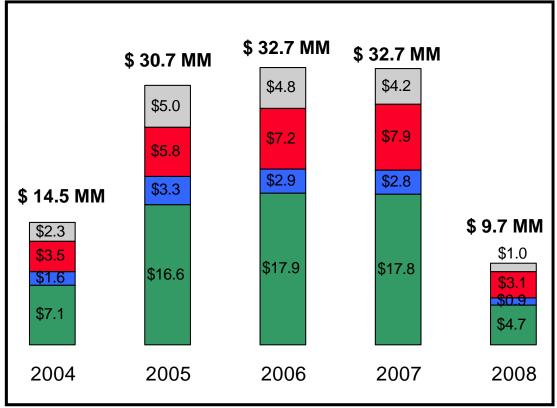
Source: Abbott Conducted Qualitative Research with MLs and Key Opinion Leaders, Fall 2002.

## Where does the growth come from?

# Change in Revenues Over 2003 Plan

# Change in Revenues Over 2004 Plan, 2005-2008 LRP\*





\*Note: The 2005-2008 LRP will be updated in December 2003.